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CLINICAL INVESTIGATION PROGRAM REPORT RCS MED-300 (R-1) 1/3

(U) DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER FORT

GORDON GA DEPT OF CLINICAL INVESTIGATION K M PLOWMAN

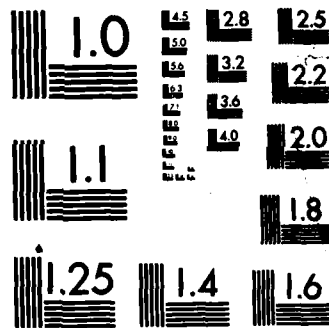
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PSYCHICAL INVESTIGATION PROGRAM REPORT

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19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Unit Summary; Detail Sheet (Study Objective, Technical Approach, Progress, Status); Publications; Presentations.		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1985, and other known publications and presentations by the Dwight David Eisenhower Army Medical Center professional staff. A detail sheet of each protocol giving the objective, technical approach, and progress is presented.		

CLINICAL INVESTIGATION

PROGRAM REPORT

1 October 1985

CONTROL SYMBOL: MED-300 (R1)

Department of Clinical Investigation
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905-5650



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FOREWORD

The physician subtly ridiculed by Geoffry Chaucer in the Prologue to the Canterbury Tales is featured on the cover of this report to illustrate some points regarding research in the training of a clinical physician.

"With us ther was a Doctour of Phisyk;
In al this world ne was ther noon him lyk
To speke of phisik and of surgerye.
For he was grounded in astronomye;
He kepte his pacient a ful greet del
In houres by his magik naturel.
Wel coude fortunen the ascendent
Of his images for his pacient.
He knew the cause of everich maladye,
Were it of hoot or cold, or moiste, or drye,
And where engendred, and of what humour;
He was a verray, parfit practisour.
The cause y-knowe, and of his harm the rote,
Anon he yaf the seke man his bote.
Ful redy hadde he his apothecaries
To sende him drogges and his letuaries,
For ech of hem made other for to winne;
Hir frendschipe nas nat newe to biginne.
Wel knew he th'olde Esculapapius,
And Deiscorides, and eek Rufus,
Old Ypocras, Haly, and Galien,
Serapion, Razis, and Avicen,
Averrois, Damascien, and Constantyn,
Bernard, and Gatesden, and Gilbertyn.
Of his diete mesurable was he,
For it was of no superfluitee,
But of greet norissing and digestible.
His studie was but litel on the Bible.
In sangwin and in pers he clad was al,
Lyned with taffata and with sendal;
And yet he was but esy of dispence;
He kepte that he wan in pestilence.
For gold in phisik is a cordial,
Therefore he lovede gold in special."

The historical figure identified as the Aesculapius spouting "doctour of phisyk" is Dr. John Gaddesden, author of Rosa Anglica. Chaucer, as a medical layman, was able to see through the "scientific" pretensions of his subject who tried to represent himself as an erudite medical practitioner. Dr. Guy de Chauliac, the French surgeon, also leveled blistering critiques at Rosa Anglica as children's fables that failed to be sweet smelling. My own righteous indignation at modern day equivalents of Aesculapius quoters and urine casters has been well ventilated in these columns before and does not require further protestations.

Rather, a different lesson can be learned from Dr. Gaddesden than one of heaping more abuse on his pretensions. By some unknown means, he happened onto the ultra-red light theory for treating smallpox five hundred years ahead of its general recognition. He treated Prince John for smallpox by wrapping him in red cloth and hanging red curtains about his bed and sickchambers. We have no way of knowing whether he had fashioned some astute observations whose merits were not recognized because of his profligacy, or whether one of his fables was true merely by happenstance. Rather than speculating further on whether this is an example of chance favoring the prepared mind, we should more profitably reflect on the modern dilemma of medicine with its strong pathophysiologic basis albeit dehumanized delivery.

The present generation of physicians has been well trained in the explicatory phase of medicine with its diagnostic titles for diseases and its pathophysiologic explanations and etiologies. This scientific aspect has made enormous contributions to medicine over the past decades and centuries. It is solidly related to all of natural science by a broad theoretical and practical base. Based on this new "humoral theory," the modern physician also knows, "...the cause of everich maladye, and where engendered, and of what humour,..."

The correspondingly mighty therapeutic armamentarium has radically altered the managerial phase of medicine. Interventions in clinical problems are now frequently so powerful that one may prevent many future complications, sometimes even with full restoration of health. Despite this improved therapeutic success, the mutual profitability between the "doctours" and the "apothecaries" engenders occasional scepticism even today. Patients have come to view the physicians love affair with drugs and science as detracting from the humanistic qualities of clinical care. Technology use by physicians all too frequently tends to replace human perceptivity and to cloud the sensitive concern for the intensely personal problems of sick patients. If the merely biologic phase is treated correctly, one need not worry about the psyche unless it is demented.

The difficulty is not with basic science or technology themselves but with the failure to apply their precepts to clinical management. As Dr. Alvan R. Feinstein has argued, basic biomedical science has its operating paradigms so arranged that a basic science of clinical management is excluded by these barriers. Cogent human information items, such as limiting symptoms and personal problems, are systematically rejected and placed outside the boundary of science. The "soft" data of the patient's discomfort, joy, sorrow, fear, or insomnia are systematically excluded as unworthy. The reductionist mentality of the technologist is all too likely to treat human conditions as essentially equivalent to the corresponding animal model or as no more than the sum of his organ systems. Those qualities that are uniquely human and transcendent are seen as irrelevant for his diagnostic acumen.

Most studies of coronary artery disease, for example, focus on the anatomy and physiology of the coronary arteries, ventricular contraction, and the conducting system. Few studies are concerned about whether the patient was symptomless, had mild angina, or had severe and persistent retrosternal pain.

Was the patient able to work? How long have the symptoms been progressing? What other diseases co-exist with the condition? Why did the patient seek medical care when he/she did? Was medical treatment given because the doctor believed surgery was contraindicated or because the patient refused surgical treatment? Is the CAD patient not working because of severe angina limiting his activities, because of his doctor's orders, or because of the patient's own fears? If he returns to work after bypass surgery, these answers might be important. What is the longevity of his parents? What is the temperament of the patient? What is the skill of the surgeon or the compliance of the patient? What happened to certain intermediate target goals such as blood pressure or blood glucose during the followup period? What cointerventions were used?

Great questions remain to be answered by physicians willing to conduct clinical science in an area that can bridge the historical gap between reductionist science and humanitarian medical art. This new science of clinical management has different paradigms from the usual basic biomedical science. In the latter, great imagination is needed to formulate the hypotheses and counter-hypotheses for the underlying mechanism. The methodology is usually relatively straightforward. The science of clinical management, on the other hand, requires little imagination to formulate the hypotheses and counter-hypotheses. It does demand imaginative solutions to the problems of measurement. The appropriate patient groupings, the data to be collected, the variables to be controlled, and the treatment protocol to be followed may all require new approaches. These issues form the major challenge for designing a good clinical study.

Physicians now in training would benefit from a solid grounding in those skills that allow them to assess the value of their interventions under specific protocols. Current cost containment strategies may increasingly force medicine to study these issues with a new urgency. Physicians trained in those skills of clinical management are desperately needed to identify the profile of patients who can most benefit from scarce interventions. The decisions will be tough. Some basis other than availability of therapy and ability to pay must be found to allocate scarce resources. Third party payers are even now beginning to balk at the cost associated with the indiscriminate use of technologically superb medical care. Physicians will then need to know how to design these clinical management studies and to understand them in the medical literature if they are to practice the best quality medicine. Hopefully, such information will permit humanitarian qualities once again to be factored back into medicine in a structured way. Thoughtful, skilled physicians may then be able to regain control over the reductionist forces at work in a superb, biomedically proficient medicine capable of tuning the human machine as precisely as an old Ferrari. These human factor data will not be available to aid in such decisions if the properly designed studies have not been performed. We in the military have a unique opportunity to play an important role because of the potential for obtaining some of these data in our relatively more controlled population.

Army medicine, as practiced at Eisenhower Army Medical Center under Brigadier General Alcide M. LaNoue, has this type of broad excellence as its

goal. Not only must the best technical medicine be practiced, but it must be performed in a caring manner, desiring the best for each individual with his or her unique problems, fears, hopes, and limitations. Our physicians in training are being imbued with these values in a way that Chaucer could be paraphrased to say "For vertu in phisik is a cordial, therefore, they lovede vertu in special."



KENT M. PLOWMAN, M.D., PhD
LTC, MC
Chief, Department of Clinical Investigation

G. Chaucer, "Prologue" The Canterbury Tales.

A.R. Feinstein, "An Additional Basic Science for Clinical Medicine:" Ann Int Med 1983; 99:393-397, 544-550, 705-712, 843-848.

UNIT SUMMARY - FISCAL YEAR 1985

A. Objective.

The Department of Clinical Investigation is responsible to the Deputy Commander for Clinical Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigation within DDEAMC.

B. Technical Approach.

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing.

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Plowman, Kent, M.	LTC	61F00	Chief
Yancey, Anthony	MAJ	64F00	Veterinarian
Harris, Richard W.*	MAJ	68A00	Microbiologist
Sherman, Richard A.	CPT	68T9C	Psychobiologist
Mereish, Kulthoum A.	CPT	68C00	Biochemist
Losier, Andrew J., Jr.	SFC	92B20	NCOIC
Hobbs, Carroll	SGT	92B20	Med Lab Sp
Gauthier, Peter A.	SGT	92D10	Chem Lab Sp
Lugo, Jesus	SGT	92D10	Chem Lab Sp
Bilal, Omar	SP4	91T10	Animal Sp
McCullers, Manuela	SP4	91T10	Animal Sp
Horner, Jack A.	GM13	01301	Asst C, S. Res Histologist
McPherson, James C. III, PhD	GS12	01320	Biochemist
Prior, Robert	GS11	00644	Medical Technologist
Harrison, Katherine	GS9	00181	Psychology Technician (Temp)
Hinton, Alma	GS7	00404	Biological Lab Technician
Martinez, Rosina	GS7	03030	Clinical Protocol Coordinator
Silas, Billy E.	GS6	04040	Biological Lab Technician
Ferrell, Sandra	GS4	00312	Clerk Steno
Challenger, Patricia	GS11		Study Coordinator (5-yr term Dermatology Svc, NIH Grant)
Bruno, Glenda	GS9	00644	Medical Technician (3-yr term, Dept of Clinical Investigation, VA Grant)

*PCS Aug 85

D. Funding.

Type	Fiscal Year 84	Fiscal Year 85
Civilian personnel to include benefits	165,175.00	215,435.00
Consumable supplies	87,534.00	82,152.00
Civilian contracts to include consultants	11,502.00	10,463.00
TDY*	6,000.00	4,705.00
Publications	2,102.00	2,414.00
Noninvestment equipment (Minor MEDCASE)	15,634.00	
Other OMA	13,257.00	
OMA Total	28,891.00	26,614.00
MEDCASE	117,778.00	57,897.00
Other		
Military	301,070.00	399,960.00
Total	748,943.00	799,640.00

*Includes Clinical Investigation personnel plus other paper presentations from Dwight David Eisenhower Army Medical Center staff and residents.

E. Progress.

Protocol Disposition FY 85

	<u>Completed</u>	<u>Terminated</u>	<u>Ongoing to FY 86</u>
FY 78	-	-	2
FY 79	-	-	3
FY 80	2	-	-
FY 81	-	-	4
FY 82	7	1	2
FY 83	2	3	7
FY 84	54	2	12
FY 85	6	2	30
	<u>71</u>	<u>8</u>	<u>60</u>

Two of the ongoing FY 85 studies above are pending approval at HSC.

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PUBLICATIONS FY 85

DEPUTY COMMANDER FOR CLINICAL SERVICES

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Code:

(C) - Results of clinical study

PRESENTATIONS FY 85

1985 Recipient of the Annual Resident Research Award: CPT James A. Classen, MC, Dept of Surgery, for his paper entitled "Effect of Prophylactic Metronidazole or Cefoxitin Versus Placebo in Preventing Wound Infection in Nonperforated Appendicitis."

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Prior RW, McPherson JC III, Yancey AL, Ward DF, Kirby SG, McPherson JC Jr: The effect of tetronic 707 on osmotic and mechanical fragilities of rat red blood cells. Georgia Academy Science, Carrollton, GA, 26-27 Apr 1985. (C)

Silas BE, Plowman KM, Yancey AL, Prior RW, McPherson JC Jr, McPherson JC III: Canine alternatives in biomedical research: Swine and goats. Georgia Academy Science, Carrollton, GA, 26-27 Apr 1985. (C)

Gauthier PA, McPherson JC III, Yancey AL, Kirby SG, Ward DF, McPherson JC Jr: The mechanical fragility of dog red blood cells using a modified method and the effect of pluronic F-68 on dog red blood cells. Georgia Academy Science, Carrollton, GA, 26-27 Apr 1985. (C)

McPherson JC III, McPherson JC Jr: Serum gastrin, cholesterol and triglyceride levels in the cobalt chloride treated rat. 67th Annual Meeting Endocrine Soc, Baltimore, MD, 19-21 Jun 1985. (C)

McPherson JC III, Ward DF, Kirby SG, McPherson JC Jr: The influence of cobalt ion concentration on rat red blood cell mechanical fragility. Annual Conference Georgia Nutrition Council, Atlanta, GA, 21-22 Mar 1985. (C)

Gauthier PA, McPherson JC III, McPherson JC Jr: Serum lipoprotein disassociation by pluronic F-127. Annual Conference Georgia Nutrition Council, Atlanta, GA, 21-22 Mar 1985. (C)

Prior RW, Gauthier PA, McPherson JC Jr, McPherson JC III: Cholesterol and triglyceride values in the cobalt chloride treated rat. Annual Conference Georgia Nutrition Council, Atlanta, GA, 21-22 Mar 1985. (C)

McPherson JC Jr, Prior RW, McPherson JC III: Comparative effects of triton WR-1339 and pluronic F-127 on serum gastrin levels in fed and non-fed fasted rats. Annual Conference Georgia Nutrition Council, Atlanta, GA, 21-22 Mar 1985. (C)

Kirby SG, Ward DF, McPherson JC Jr, Yancey AL, McPherson JC III: Effect of acetylphenylhydrazine on mechanical fragility of rat red blood cells and the protective effect of pluronic F-68. Georgia Academy Science, Carrollton, GA, 26-27 Apr 1985. (C)

Matthews PS, Ward DF, Kirby SG, McPherson JC Jr, Yancey AL, McPherson JC III: Effect of calcium ion concentration on mechanical fragility of rat red blood cells. Georgia Academy Science, Carrollton, GA, 26-27 Apr 1985. (C)

McPherson JC Jr, Kirby SG, Ward DF, Yancey AL, McPherson JC III: The influence of osmolality on the mechanical fragility of rat red blood cells. Georgia Academy Science, Carrollton, GA, 26-27 Apr 1985. (C)

Rissing JP Buxton TB, Harris RW, Shockley K: Bimicrobial experimental Staphylococcus aureus osteomyelitis in rats: Facilitation of infection by B. fragilis. ICACC, Washington, DC, 8-10 Oct 1984. (C)

Harris RW, Shockley RK, Hobbs CE, Morrison RE: Relationship of protein-binding of b-lactams to penetration into subcutaneous and intraperitoneal extravascular fluid. American Soc Microbiology, Las Vegas, NV, 7 Mar 1985. (C)

Doetsch GS, Johnston KW, Hannan CJ: Changes in functional organization of the somatosensory cortex of adult racoons following restricted cortical lesions. Society Neuroscience, Anaheim, CA, Nov 1984. (C)

Yancey AL, Plowman KM, Silas BE, McPherson JC III: The osmotic and mechanical fragilities of pig red blood cells and the effect of pluronic F-68 comparison with dog and rat cells. Annual Meeting Swine in Biomedical Research, College Park, MD, 17-20 Jun 1985. (C)

Yancey AL, McPherson JC III, Ward DF, Kirby SG, McPherson JC Jr: Influence of pluronic polyols on rat red blood cell membranes: Effect on osmotic fragility. Society Experimental Biology Med, Tampa, FL, 8-9 Nov 1984. (C)

Mereish KA: The interstitial absorption of cyclosporine (Sandimmunetm). Invited Guest Speaker, LAIR, San Francisco, CA, 22 Aug 1985. (C)

Gale T, Horner JA: Teratologic effects of cadmium on developing hamster embryos. Southeast Teratologic Soc, Calloway Gardens, GA, Mar 1985. (C)

Sherman RA, Ernst JL, Markowski J: Relationships between near surface blood flow and phantom body pain among spinal cord injured veterans. American Paraplegia Society, Las Vegas, NV, 3-6 Sep 1985. (C)

Gale TF, Horner JA: Effects of cadmium on early facial development in hamsters: Surface area measurements. Southeast Electron Microscopy Soc, Augusta, GA, May 1985. (C)

Gale TF, Horner JA: Effect of cadmium on the facial prominences of hamster embryos. Preliminary findings. Teratology Soc Meeting, Jul 1985. (C)

Horner JA: Effects of fluoride on the gastric mucosa of the rat. Southeast Electron Microscopy Soc, Augusta, GA, May 1985. (C)

Horner JA: Hosted and conducted Regional Symposia (Workshop) on Microanalysis in the Electron Microscope, Augusta, GA, May 1985.

DENTAL ACTIVITY

Hartwell GR: Vertical root extrusion: A multidiscipline approach to treatment. Fort Jackson Dental Activity and Columbia, South Carolina Dental Society Continuing Education Meeting, Fort Jackson, SC, Oct 1984.

Hartwell GR: Diagnosis and management of perio-endo lesions. Endodontic Short Course, WRAMC, Washington, DC, Oct 1984.

Hartwell GR: Clinical management of fracture and perforating coronal root defects. Endodontic Short Course, WRAMC, Washington, DC, Oct 1984.

Hartwell GR: Diagnosis of perio-endo lesions. Dental Activity Continuing Education Meeting, Fort Stewart, GA, Jan 1985.

Hartwell GR: Vertical root extrusion techniques. Dental Activity Continuing Education Meeting, Fort McPherson, GA, Apr 1985.

Hartwell GR: Perio-endo lesions: A diagnostic dilemma. Round Table Seminar, Annual Meeting Am Assn Endodontists, San Diego, CA, Apr 1985.

Hartwell GR: Vertical root extrusion techniques for the general dentist. Dental Activity Continuing Education Meeting, Fort Bragg, NC, May 1985.

DEPARTMENT OF FAMILY PRACTICE

Madlon-Kay DJ: Evaluation and outcome of the dizzy patient. USAFP Annual Meeting, Williamsburg, VA, 1985.

DEPARTMENT OF MEDICINE

Office of the Chief

Morrison RE, Harris RW, Hobbs CE: Subcutaneous and intraperitoneal penetration of cefoperazone. ICAAC Annual Meeting, Washington, DC, Oct 1984. (C)

Morrison RE: What's new with chlamydia. Eighth Southeastern Consortium Continuing Education in Dermatology. In Association with the Carolinas-Virginia Dermatologic Society. Augusta, GA, Oct 1984.

Harris RW, Shockley RK, Hobbs CE, Morrison RE: Relationship of protein-binding of beta-lactams to penetration into subcutaneous and intraperitoneal extravascular fluid. Am Soc Microbiology, Las Vegas, NV, 7 Mar 1985. (C)

Dermatology Service

Aton A: Current therapy of syphilis. Eighth Southeastern Consortium Continuing Education in Dermatology. In Association with the Carolinas-Virginia Dermatologic Society. Augusta, GA, Oct 1984.

Cook JR: Metabolic disorders. Eighth Southeastern Consortium Continuing Education in Dermatology. In Association with the Carolinas-Virginia Dermatologic Society. Augusta, GA, Oct 1984.

Guill MA: Skin manifestations of renal disease. Eighth Southeastern Consortium Continuing Education in Dermatology. In Association with the Carolinas-Virginia Dermatologic Society. Augusta, GA, Oct 1984.

Aton JK, Guill MA: Atypical fibrous histiocytoma. Zola Cooper Clinicopathologic Seminar, Southern Med Assn, New Orleans, LA, Nov 1984.

Kent DE, Cook JR, Klein AD, Guill MA: Alveolar rhabdomyosarcoma. Southern Med Assn, New Orleans, LA, Nov 1984.

Guill MA: Common dermatologic problems, venereal disease. Richmond County Health Department, Augusta, GA, May 1985.

Guill MA: Common skin disorders. 91C School, Fort Gordon, GA, Mar 1985.

Nephrology Service

Bennett R: Acute renal failure requiring hemodialysis. Current Concepts in Internal Medicine, Nephrology Subsection, San Francisco, CA, 1-5 Oct 1984.

Nuclear Medicine

Kaplan KA: Nuclear medicine review course. Co-Chairman, 32d Annual Society Nuclear Medicine National Meeting, Houston, TX, 2-5 Jun 1985.

Kaplan KA: Radiation accident management. 32d Annual Society Nuclear Medicine National Meeting, Houston, TX, 4 Jun 1985.

Hardin V: Lung function and imaging studies using new radioaerosol technique. Augusta Nuclear Technologists Society, Augusta, GA, May 1985.

DEPARTMENT OF PATHOLOGY

Lawn RT: Transfusion history/blood component therapy. Georgia Soc Med Technologists, Macon, GA, 11 May 1985.

Weir GT: Blood component utilization. Georgia Soc Med Technologists, Macon, GA, 11 May 1985.

DEPARTMENT OF PEDIATRICS

Wientzer RL, Benton FR, Butler K, Ziai M: Elimination of Hemophilus influenzae type b pharyngeal carriage from index cases of HIB invasive disease: Comparison of two rifampin strategies. 24th International Conf Antimicrobial Agents Chemotherapy, Washington, DC, Oct 1984.

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

Blanco AF: Working with terminally ill children. GEN William C. Menninger Mem Conf: Armed Forces Mil Psychiatry Conf, Topeka, KS, 15 May 1985.

Blanco AF: The childhood of Miguel de Corvantes: A study on autistic creativity. Senior Resident Fellow Research Symposium, WRAMC, Washington, DC, 9 Jun 1985.

Blanco AF: Treatment of minority families. Catholic University, Washington, DC, Mar 1985.

Deeken MG, Eshbach RS: Inpatient rehabilitation of alcoholic soldiers. 31st International Institute Prevention Treatment Alcoholism, Meeting International Council on Alcohol and Addictions. Rome, Italy, 6 Jun 1985.

Gagon TE: Variables affecting psychotherapy in the military. GEN William C. Menninger Mem Conf: Armed Forces Mil Psychiatry Conf, Topeka, KS, 14 May 1985.

Gagon TE: The normative crisis of the adult life cycle. Panama, 13 Jun 1985.

Haskin JJ: Fit to fight, fit to psych: Psychiatry in the deployed division. AMEDD Division and Combat Psychiatry Short Course, Fort Bragg, NC, 3 Dec 1984.

Haskin JJ: Suicide prevention and mental status examination. USFK/EUSA Alcohol and Drug Abuse Prevention and Control Program Clinical Conf, Seoul, Korea, 3 May 1985.

Hoffer RS: Chronic pain. University of Alabama, Birmingham, AL 26 Apr 1985.

Jensen PS: Academic pursuits: Career alternatives. Forum APA Annual Meeting, 1985.

Wymes MB, Jensen PS, et al: Resident and faculty perceptions of support. Workshop presented at APA Annual Meeting, 1985.

Marcum JM: Chance discovery of multiple personality disorder during an amytal interview - A case report. GEN William C. Menninger Mem Conf: Armed Forces Mil Psychiatry Conf, Topeka, KS, 16 May 1985.

SOCIAL WORK SERVICE

Maury JL: Military social work. East Central District Hospital Social Work, Eisenhower Army Medical Center, Nov 1984.

Maury JL: Spouse abuse treatment programs. Eisenhower Regional Social Work Conference. Eisenhower Army Medical Center, 23-24 Jan 1985.

Maury JL: Treatment issues in child abuse/neglect cases. Eisenhower Regional Social Work Conference. Eisenhower Army Medical Center, 23-24 Jan 1985.

Maury JL: Treatment issues with alcohol/drug patient and family. National Association Social Work, Georgia Chapter Conference, Augusta, GA, 29 Mar 1985.

Maury JL: Future practice issues in Army Social Work. Army Social Work Conference, WRAMC, Washington, DC, 26 Mar 1985.

Dalton P: Spouse abuse treatment programs. Eisenhower Regional Social Work Conference. Eisenhower Army Medical Center, 23-24 Jan 1985.

Dalton P: Treatment issues in child abuse/neglect cases. Eisenhower Regional Social Work Conference. Eisenhower Army Medical Center, 23-24 Jan 1985.

Dalton P: Child and spouse abuse. Military Police Company, Ft Gordon, GA, Apr 1985.

Dalton P: Child sexual abuse. Post Commanders Conference, Ft Gordon, GA, Aug 1985.

DEPARTMENT OF SURGERY

Anesthesia and Operative Service

Parker EO: Electrosurgical burns. Assn Advancement Medical Instrumentation, Boston, MA, 3-5 May 1985.

Parker EO: Clinical use of sufentanil in balanced anesthesia for general surgery. South Carolina Society Anesthesiologists, Charleston, SC, Apr 1985.

Audiology

Bender DR: Factors influencing the decision to obtain amplification. Am Speech-Language Hearing Assn, San Francisco, CA, Nov 1984. (C)

General Surgery Service

Brigham RA: Scientific Exhibit - Inflammatory aneurysms of the abdominal aorta. Am College Surgeons Clinical Congress, San Francisco, CA, 21-26 Oct 1985 and Southeastern Surgical Congress, Washington, DC, 17-20 Mar 1985.

Brigham RA: Inflammatory aneurysms of the abdominal aorta. Assn Military Vascular Surgeons, Bethesda, MD, 29-30 Nov 1984.

Brigham RA: Scientific Exhibit - Extended profunda femoris revascularization. Southeastern Surgical Congress, Washington, DC 17-20 Mar 1985.

Steely WM: Sclerosing mesocolitis. Gary Wratten Symposium, San Antonio, TX, 8-10 Apr 1985.

Orthopedic Surgery Service

Barja RH: Silastic trapezium implant: A new technique. Virginia Orthopedic Assn, 1 May 1985.

Donovan LT, Smith DS, Warncke RM, Shade RD: Femoral neck stress: The need for prophylactic knowles pinning. Southern Orthoped Assn, New Orleans, LA, Nov 1984. Am Academy Orthop Surg, Atlanta, GA, 1984.

Goodrich JA: Metastatic Tumors of the Hand: A Report of Two Cases and Literature Review. Southern Orthopedic Assn Annual Residents' and Fellows' Conference, New Orleans, LA, Nov 1984.

Goodrich JA: Intradural Dermoid Cyst: A Case Report. SOMOS, Colorado Springs, CO, Nov 1984.

Donovan LT: Routine Adult Skeletal Radiography: Do You Really Know It? Part II Am Academy Orthop Surg, Atlanta, GA, 1984. Part III Am Academy Orthop Surg, Las Vegas, NV, 1985.

Otolaryngology Service

Belmont JR: Laryngeal dysgenesis. Annual Meeting Am Laryngological Assn, Miami Beach, FL, 26 May 1985.

Belmont JR: Sphenoid bone fracture. XIII World Congress Otorhinolaryngology-Head and Neck Surgery, Miami Beach, FL, 26-31 May 1985.

Belmont JR: Optic nerve trauma and treatment. Course Faculty, Maxillofacial Trauma Course, Tripler Army Medical Center, Honolulu, HI, 11-13 Feb 1985.

COMMUNITY MENTAL HEALTH SERVICE

Gregory GA: The behavior of soldiers in battle (Combat motivation). AMEDD Division Combat Psychiatry Course, Ft Bragg, NC, Dec 1984.

Gregory GA: History, current concepts and future of combat psychiatry in the USA. Hospital Militar Central, Lima, Peru; Naval Hospital, Lima, Peru, 16 May 1985.

Gregory GA: Spectrum of disorders in combat reactions. Hospital Militar Central, Lima, Peru; Naval Hospital, Lima, Peru, 23 May 1985.

Gregory GA: Motivation for combat. Hospital Militar Central, Lima, Peru; Naval Hospital, Lima, Peru; Commander and General Staff, Peruvian Marine Corp, Ancon, Peru. 29-30 May 1985.

MARTIN ARMY COMMUNITY HOSPITAL FORT BENNING, GEORGIA

Saultz JW, Wright JB: Why do patients choose a family physician? Ressearch Forum, Southeast Regional Meeting Soc Teachers of Fam Med, Atlanta, GA Oct 1984.

Saultz JW: An introduction to medical ethics. Ann Residency Retreat, Atlanta, GA, May 1985.

Saultz JW: Teaching family systems medicine. Ann Clerkship Coordinator's Workshop, Uniformed Services University of Health Sciences, Bethesda, MD, Sep 1985.

Saultz JW, Henderson JM: The fiberoptic flexible sigmoidoscope. Workshop for Family Physicians, Eisenhower Army Medical Center, Sep 1985.

Fogarty JP: Combat Lifesaver training in 2d Armored Division. FORSCOM Surgeon's Meeting, Atlanta, GA, Apr 1985.

Epperly TD: The value of needle aspiration in the diagnosis of cellulitis. Fam Prac Teaching Fellowship, Univ NC, Chapel Hill, NC, Jun 1985.

Henderson JM: Heat stroke: Historical, military, and clinic significance. USAFP XIth Ann Scientific Session, Williamsburg, VA, Mar 1985.
Tropical Medicine Course, WRAIR, Washington, DC, Jul 1985.

Prohaska GM: Posterior urethral valves: A case report. Scientific Session Georgia Academy Fam Practice, Stone Mountain, GA, May 1985.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 79-7 Status: Ongoing
 Title: Control of Gonadotropin Secretion in the Male Rat.

Start Date: May 79		Est Comp Date:
Principal Investigator(s) James C. McPherson III, PhD		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words: Gonadotropins Steroids		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the role of estrogens, progestins and androgens either alone or in combination in the regulation of gonadotropin secretion.

Technical Approach: Immature male and female rats and neonatally androgenized female rats are castrated and given replacement steroid therapy beginning immediately and continuing for five days. These animal models are utilized to study the effects of various steroids both individually and in combination on the control of gonadotropin secretion, including the pituitary sensitivity to LHRH, peptide and neurotransmitter roles. Secondary sex organs are removed and weighed as a measure of biological activity of the steroids. Serum and tissue samples are analyzed for a variety of endocrine components including gonadotropins, peptides, steroids and neurotransmitters.

Progress: New HPLC techniques are being investigated for the measurement of steroids and neurotransmitters. Additional techniques are being investigated for the measurement of the binding capabilities of LHRH and neurotransmitters.

Detail Summary Sheet

Date: 2 Oct 85 Prot No.: 79-19 Status: Ongoing
 Title: Gastrointestinal Hormones in Non-Ionic Surface Active Agent Induced Delay of Gastric Emptying.

Start Date: Jan 80		Est Comp Date:
Principal Investigator(s) James C. McPherson III, PhD, DAC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators: James C. McPherson, Jr., M.D., Medical College of Georgia
Key Words: Gastric emptying Surfactants Gastric secretion		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the effect of non-ionic surface active agents on gastric emptying, voluntary food consumption, body weight and blood chemistries.

Technical Approach: Groups of fasted rats were given non-ionic surface active agents followed 30 minutes later by a commercial rat tube feeding diet. Animals were sacrificed at various times after feeding and gastric emptying compared to control groups. In another series of experiments, rats were injected daily for four days with non-ionic surface active agents. Voluntary food consumption before and during treatment was measured. Twenty-four hours following the last injection, the animals were sacrificed and blood drawn for blood chemistries. In an additional series of experiments the effect of non-ionic surface active agents on gastric secretion is being assessed. Cimetidine, a known gastric secretion inhibitor and metoclopramide, a known agent that stimulates motility of the upper gastrointestinal tract without stimulating gastric secretion, have been utilized to access the actions of these non-ionic surface active agents on delayed gastric emptying. Serum gastrin levels were assayed by radioimmunoassay in fed and non-fed rats given saline or Triton WR-1339 (a non-ionic surface active agent which delays gastric emptying).

Progress: Intravenously administered Triton WR-1339, a non-ionic surface active agent, has been used as an endogenous hyperlipemic agent since 1951. We expected Triton to increase food consumption to, at least partially, supply the energy and acetyl groups necessary for producing the hyperlipemic state. In this study, however, we observed the rats injected intravenously with various dose levels of Triton decreased their voluntary food intake in a dose related manner. Two other non-ionic surface active agents, Tween 20 and Tween 80, given intravenously did not alter food intake. Further studies revealed that Triton WR-1339 administered intravenously 30 minutes before feeding by stomach tube resulted in a marked delay in the rate of gastric emptying which was also dose related. A delay in gastric emptying has previously been

suggested as one mechanism that controls food intake. Tween 20 and Tween 80 did not alter the rate of gastric emptying. We suggest that the mechanism responsible for the decrease in voluntary food consumption in Triton WR-1339 injected rats may be due to the delay of gastric emptying in these animals.

The control of gastric secretion and emptying has been recognized to be under the control of various gastrointestinal hormones. We have shown Triton WR-1339 to delay gastric emptying, increase gastric secretion and sustain increased levels of serum gastrin, cholesterol and triglyceride and Pluronic F-127, another non-ionic surfactant, to further significantly increase levels of serum gastrin, cholesterol and triglyceride (all $p < 0.01$) associated with normal gastric emptying. To determine if these elevated gastrin levels were due to drug action or induced by hyperlipemia, male Sprague-Dawley rats were given cobalt chloride, 4 mg/100g body weight by subcutaneous injection once a day on each of ten days with an interval of nine days between the fifth and sixth injections. A group of six rats were sacrificed by cardiac puncture each day for 32 days starting on day zero and the serum analyzed for cholesterol and triglyceride using a Technicon RA-1000 and serum gastrin measured by RIA. Cobalt chloride induced hyperlipemia resulted in a 40.7% increase in cholesterol ($p < 0.01$) and a 67.7% increase in triglyceride ($p < 0.01$) levels over control levels during each injection period. Significant reductions in circulating serum gastrin levels ($p < 0.01$), up to 184%, occurred during each injection period and remained significantly reduced ($p < 0.01$) following the second injection period through day 32. These results suggest that increased circulating levels of gastrin are not associated with hyperlipemia as may have been concluded from our previous results. Therefore, Triton WR-1339 may be useful in studies involving induced delayed gastric emptying and elevated serum gastrin levels and Pluronic F-127 may be useful in studies of hypergastrin levels associated with normal gastric emptying.

Presentations and publications:

Influence of pluronic polyols on rat red blood cell membranes: Effect of mechanical fragility. Experi Biology and Med Society, Tampa, FL, Nov 1984. Published abstract: Proc Soc Experi Biology Med (Abstract SE Section) 1985; 179:264.

Influence of pluronic polyols on rat red blood cell membranes: Effect on osmotic fragility. Experi Biology and Med Society, Tampa, FL, Nov 1984. Published abstract: Proc Soc Experi Biology Med (Abstract SE Section) 1985; 179:263.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 79-21 Status: Ongoing
 Title: The Experimental Fat Embolism Syndrome: An Electron Microscopic Study of Lung in Three Models.

Start Date: Jun 80		Est Comp Date:
Principal Investigator(s) Jack A. Horner, B.S.		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators: James C. McPherson III, PhD James C. McPherson, Jr., M.D., Medical College of Georgia
Key words: Fat embolism Electron Microscopy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:\$1200	Periodic Review Results

Study Objective: Experimental fat embolism syndrome is usually induced by one of five techniques: 1) fracture of the femur of an animal, 2) injection of extracted or homogenized adipose tissue from a same species donor, 3) injections of olive oil or purified triolein, 4) injection of oleic acid, or 5) injection of mineral oil (all injections given intravenously). In this study the similarity and differences, if any, in these last three techniques (olive oil, oleic acid, and mineral oil) will be investigated.

Technical Approach: Fat embolism is a major (although frequently undiagnosed unless severe) complication in patients with fractures of the long bones and/or severe trauma. The etiological mechanism of this syndrome is still unsettled. The two mechanisms most widely accepted are: 1) fat from the bone marrow of fractured bones or traumatized adipose tissue enter into small broken veins and travel to the lung where blockage of the capillaries and arterioles occur, and 2) after trauma, the circulating lipoproteins in blood coalesce to form globules of fat large enough to block the capillaries of the lung. In addition, once the fat has blocked a capillary or arteriole, the pathogenic events which follow are unclear. The major effect may be a simple blockage, but some investigators believe the most harmful effects result from the release of free fatty acids from the "trapped" fat globules in the lung. This study will attempt to establish the differences which could be important in the clinical syndrome by examining a mineral oil model (pure blockage with no possible release of free fatty acid from the globules), oleic acid (effect of free fatty acid only), and olive oil (fat capable of hydrolysis to yield free fatty acids). This study may add to our basic understanding of the events in the pathogenesis of the clinical fat embolism syndrome and suggest the basis of new methods of treatment.

Progress: Full resumption of this study has been awaiting the installation of a new scanning transmission electron microscope complete with x-ray and electron energy loss spectrometers. This system has recently been completed and the study will continue in FY 86.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 80-28 Status: Completed
 Title: Antimicrobial Therapy in an Animal Abscess Model.

Start Date: Jun 81	Est Comp Date: Jun 85
Principal Investigator(s) Richard W. Harris, MAJ, MSC	Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation/Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To develop an appropriate methodology for examination of effects of antibiotics on monomicrobial and polymicrobial abscesses.

Technical Approach: In order to produce an encapsulated virulent strain, all stock organisms studied will be passed through a mouse or rat by subcutaneous injection with soft agar. The aspirated organism will then be used for rabbit inoculation. Sterile plastic capsules will be implanted intraperitoneally into New Zealand white rabbits. The animals will be kept six weeks and bacteria injected into the capsule prior to initiation of antibiotic therapy. Cost to date: \$5,000.

Progress: No reportable data for this period. Investigator PCS'd in Aug 85.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 80-29 Status: Completed
 Title: Differentiation of Bacteria in vivo by Gas Liquid Chromatography.

Start Date: Nov 81		Est Comp Date: Jun 85
Principal Investigator(s) Richard W. Harris, MAJ, MSC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine patterns of metabolite production by electron capture gas chromatography in an abscess animal model.

Technical Approach: Exudate from the rabbit model will be used to compare monomicrobial abscesses. Organisms will be implanted with soft agar and exudate will be examined upon abscess formation. Serum will be drawn for determination of metabolites.

Progress: No reportable data for the period. Investigator PCS'd Aug 85.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 81-16 Status: Ongoing
 Title: Correlations Between Amount of Information Feedback and Success of Biofeedback Treatments.

Start Date: Feb 81	Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC	Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation Psychology Service	Associate Investigators: Anthony Ficara, DDS, COL, DC Roberto Barja, MD, COL, MC Benjamin Hanson, DDS, MAJ, DC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Mar 85 Review Results Continue

Study Objective: To determine whether increasing the amount of information about muscle tension given to patients with muscular control problems will shorten treatment times and increase the overall effectiveness of the treatment.

Technical Approach: For patients with bruxism, half receive muscle tension feedback from the masseter muscle, weekly in the laboratory, and wear a masseter tension monitor nightly at home. The other half does the same with the addition of receiving feedback from the night monitor when they begin tensing their jaws. For patients with subluxation of the patella, muscle tension in the vastus medialis and lateralis will be recorded. Half will receive a combined feedback proportional to their relative tension and half will receive two independent signals juxtaposed in various ways indicating both relative and absolute muscle tension.

Number of subjects enrolled to date: 167
 Number of subjects enrolled for reporting period: 46

Progress: We completed and published our initial study of relationships between jaw pain and effectiveness of biofeedback treatments. We found that biofeedback was very effective but only for those cases in which jaw muscle tension was abnormal initially. In contrast to many studies published by psychologist working with bruxism patients referred to them from various sources, we did not find any consistent evidence of any psychological abnormalities among our subjects. There was considerable question in our own minds about the relationship between treatment success and our awareness of the patients' physiologic and emotional problems. To rectify this, we are carrying out and have almost completed a blind study of similar patients in which only the dentists know the patients' diagnoses. We simply supply a pre-set treatment which is closely monitored by the dentists. When the blind study is completed, we will terminate this portion of the study. The technique will be ready to turn over to the dentists and clinical psychology as a proven treatment for patients meeting specific entrance criteria.

81-16 Continued

The portion of this study dealing with subluxation of the patella apparently due to abnormal patterns of muscle tension is in the control stage. We have done multiple recordings of ten subjects with no history of knee problems to determine what normal patterns are as well as expected levels of intra and inter subject variability. We are currently analyzing this data. If the data support the excellent clinical results of the treatment, we will have a proven technique with demonstrated criteria for both entrance and use. If this is the case, we will terminate this portion of the study and turn the technique over to Orthopedics and Physical Therapy for clinical use. If the data do not identify objective entrance and success criteria, we will have to do further investigations to determine why the treatment works so well.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 81-18 Status: Ongoing
 Title: Environmental Stress and Electromyographic Correlates of Chronic Posterior Trunk Muscle Pain.

Start Date: Feb 81		Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation Psychology, Orthopedics		Associate Investigators: Roberto Barja, MD, COL, MC
Key Words: Low back pain Upper back pain Muscle tension		
Accumulative MEDCASE Cost: \$19,000	Est Accumulative OMA Cost:	Periodic Mar 85 Review Results Continue

Study Objective: To record those muscles in the posterior trunk of patients with lower and upper back, shoulder, or neck pain related to abnormal muscle tension in order to ascertain relationships between stress, pain, and tension as well as evaluate the effectiveness of muscular relaxation training as a treatment for these problems. The relative effectiveness of these treatments for pain in the above areas with and without underlying muscle tension problems will be evaluated.

Technical Approach: Recordings of muscle tension; objective psychosomatic measures of stress, anxiety, functional locus and other factors; discomfort logs; and other measures will be made before, during and after muscle relaxation treatments of individuals with the problems described above. These progressive measures will be compared with identical measures made of individuals with: 1) musculoskeletal related pain in other areas; 2) high anxiety but no musculoskeletal pain; and 3) posterior trunk pain but no muscle tension problem. A second phase of the study will consist of continuous muscle tension recordings made throughout the day using wearable EMG recorders. These measures will be related to a continuously tape recorded log of environmental loci and stresses.

Number of subjects enrolled to date: 277

Number of subjects enrolled for reporting period: 50

Progress: Due to lack of technical support, very little new work has been accomplished on this project this year. We completed our surface EMG studies relating recording position with EMG and pain intensity and published it. We began correlating thermographic patterns with reports of low back pain intensity and diagnosis. To date we have not been able to reproduce a consistent relationship. We frequently find relationships between report of pain intensity and thermographic recordings which remain stable over time and in which thermographic patterns change as pain intensity changes. However, we do not find this in every case with the same diagnosis and symptoms so we really do not have a clear picture of what is going on as yet.

81-18 Continued

We are working with the 67th Signal Bn to modify our survey of musculoskeletal pain occurring during field exercises to rectify defects identified during the initial trial. The survey should be ready to go out within the next two months and should be followed by distribution of "preventive" exercises shortly thereafter.

The portion of the project dealing with reevaluation of the MMPI as an accurate measure of functional components of low back pain has progressed slowly due to lack of technical support both at Eisenhower and at the VA. The VA has agreed to commit a psychologist to the project for about 10% of his time, but does not have the technical resources to share for their portion of the project. Eisenhower has no further technical support available either.

We have not begun the sections of the project dealing with correlation of the most painful positions with EMG findings or correlating 24 hour recordings of muscle tension with activity patterns.

We have applied for grant support to hire one full time technician. If this is approved, we will have sufficient support to carry out the project as planned.

Publication:

Sherman R: Relationships between strength of low back muscle contraction and reported intensity of chronic low back pain. Am J Phys Med 1985; 64(4):190-200.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 81-19 Status: Ongoing
 Title: Investigations of Chronic Phantom Pain.

Start Date: Feb 81	Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MS	Facility: Eisenhower Army Medical Center
Dept/Svc:	Associate Investigators: Norman Gall, M.D., AMVAH San Antonio
Clinical Investigation	Roberto H. Barja, M.D., COL, MC
Key Words: Phantom pain	Jeff Ernst, PhD, VA, Augusta
Accumulative MEDCASE Cost: \$18,000	Est Accumulative OMA Cost: \$900
	Periodic Mar 85 Review Results Continue

Study Objective: 1) Develop an understanding of the underlying causes of phantom pain; 2) determine the extent of phantom pain among the amputee population; 3) develop comparative differential profiles of amputees with and without phantom pain; and 4) evaluate new treatments of phantom pain.

Technical Approach: All service connected amputees who can be located receive a mail survey requesting information about their amputation, stump pain, phantom pain, etc. All service connected veterans living near DDEAMC and all amputees treated at DDEAMC or VAMC Augusta are asked to participate in a psychometric and psychophysiologic profile. All phantom pain patients seen at any participating center receive the same profile as part of the pretreatment workup.

Number of subjects enrolled this reporting period: 26

Progress: Phantom body pain: In 34 consecutive complete spinal cord injured patients, we found absolute correspondence between abnormal thermographic patterns and reports of pain below the level of normal sensation. Next year, we will do multiple recordings of these patients to determine correlations between pain intensity and thermographic patterns. These results have caused us to reconsider basic mechanisms by which pain sensations are carried from the periphery to the brain.

Phantom limb pain: We have completed our trial survey of 1,200 veteran amputees which assessed the ability to recognize physiological and environmental facts related to changes in intensity of phantom limb pain. About half reported that they could confidently predict either or both environmental or physical variables which either initiated episodes of or altered the intensity of phantom limb pain. This survey included the Internal-External Locus of Control scale. There was no correlation between claim to be aware of factors altering phantom pain and need for control of what happens. Over 60 of the respondents have kept logs of their pain intensity, physical factors which might affect the pain, and various aspects of the weather for over four months. They are expected to keep these logs for another two months. We have sent out the finalized version of the survey to 5,000 veteran amputees. The

finalized version substitutes a section on effects of phantom pain on quality of life for the section of locus of control. Many of these respondents will also be asked to keep logs for six months to a year so we can be sure that we are adequately evaluating all patient notable factors likely to correlate with changes in phantom pain intensity.

We have evaluated 26 more amputees in the laboratory since last October. We have now confirmed the relationship between burning phantom limb pain and residual limb blood flow. We recorded each amputee at least four times. Thus, we were able to track changes in blood flow and pain intensity over time. When pain levels are constant, the thermographic pattern is stable even over a month's duration.

Support: This project has been supported by two grants during this fiscal year. One paid for all technical support for the phantom limb pain project (\$24,000) while the other paid for a thermograph to cover the phantom body pain work at the VA (\$39,750). We have requested grant support for two more technical positions.

Publications:

Sherman R, Sherman CA: Comparison of phantom sensations among amputees whose amputations were of civilian and military origins. Pain 1985; 21:91-97.

Sherman R: Direct evidence of a link between burning phantom limb pain and stump blood circulation. Orthopedics 1984; 7:1319-1320.

Sherman R, Ernst J, Markowski J: Relationships between near surface blood flow and altered sensations among spinal cord injured veterans. Submitted to Am J Phys Med.

Presentations:

Authors and titles as above. To the annual meeting of the American Paraplegia Society, Las Vegas, NV, Sep 1985.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 81-42 Status: Ongoing
 Title: Experimental Fat Embolism Syndrome: Basic Studies and Evaluation of
 Currently Available Therapies and New Agents.

Start Date: Oct 81		Est Comp Date:
Principal Investigator(s) James C. McPherson III, PhD		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators: Jack A. Horner Robert Prior
Key Words: Fat embolism Surfactants		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Evaluation of current therapies and new therapies for treatment of fat embolism syndrome in an experimental animal model.

Technical Approach: This project is being investigated in five phases. Metabolic evaluation of the non-ionic surface active agents is being conducted using an eleven parameter profile developed to screen these agents and analyzed by a Technicon RA-1000 (a mini-SMA instrument). The profile includes cholesterol, triglyceride, glucose, urea N, creatinine, uric acid, bilirubin, LDH, SGOT, CPK and ALT. Electrolyte blood cell indices and other parameters are under investigation or consideration.

Progress: A method for measuring the mechanical fragility of red blood cells suitable for use in small laboratory animals (rats) has been developed because of lack of such data in the literature. This method is also suitable for pediatric samples. Whole blood is mixed with phosphate buffered saline in a tube containing glass beads. The tubes are rocked for 90 minutes, centrifuged and the per cent hemolysis determined. Varying the osmolality of the saline suspending medium had little effect on the mechanical fragility of rat red cells prior to the NaCl concentrations at which time a significant change in osmotic hemolysis occurred. The duration of rocking increased the mechanical fragility. Varying the pH (6.4 - 8.0) had no effect. The size of the glass beads changed the mechanical fragility as did varying temperature. The mean mechanical fragility of rat red blood cells was 46% hemolysis (80 adult male animals). Because of the small volume of blood required with this method, mechanical fragility of red cells of other small laboratory animals may also be determined.

Because increasing emphasis is being placed on development of alternative animals to dogs and cats in biomedical research protocols and residency teaching programs, swine were investigated for use as a suitable substitute for these species. The osmotic fragility (O.F.) of red blood cells of swine has been reported as being more fragile than those of dogs and rats. We found no reports of swine RBC mechanical fragility (M.F.). In this study, O.F. of swine RBC's was measured by adding 25 μ l of whole blood to 5 ml of various dilutions of buffered saline (PBS) and to 5 ml of 1% Pluronic F-68 in PBS

of the same osmolalities. After 30 minutes, the tubes were centrifuged and the freed Hb measured at 540 nm (F Hb). Total Hb was determined by hemolyzing the RBC pellet, mixed and measured at 540 nm (T Hb). The per cent hemolysis (Hem) was calculated, $F\text{ Hb}/T\text{ Hb} \times 100$. Tubes of similarly prepared RBC suspensions containing three glass beads were placed on a tube rocker for 90 minutes and the per cent Hem measured for determining the M.F. Hem in PBS in both O.F. and M.F. tests became visible in 0.65% PBS and 50% Hem between 0.60 and 0.57% PBS. Hem in F-68 was not different from those in PBS in either test. Dog and rat RBC's showed visible Hem in 0.505 PBS. M.F. of rat RBC's is 50% and of dog RBC's is 13% compared to 1% of swine RBC's using the tube rocker technique. F-68 protected both dog and rat RBC's from M.F., but exhibited no effect on swine RBC's. Swine RBC's are more resistant to M.F. than those of dogs and rats, but are less resistant to O.F.

Additional studies have investigated the effect of acetylphenylhydrazine on the mechanical fragility of red blood cells and the protective effect of Pluronic F-68; the effect of polyvinylpyrrolidone, dextran and calcium ion concentration on the mechanical fragility of red blood cells; the influence of Pluronic polyols on red blood cell mechanical and osmotic fragility; and the influence of osmolality on the mechanical fragility of red blood cells.

Publications and presentations:

The dose response of pluronic F-68 on mechanical fragility of rat red blood cells. Experi Biology and Med Soc, Tampa, FL, Nov 1984.
Published abstract: Proc Soc Experi Biology Med (Abstract SE Section) 1985; 179:263.

Effect of polyvinylpyrrolidone on mechanical fragility of rat red blood cells. Georgia Academy Science, Carrollton, GA, Apr 1985.
Published abstract: Georgia J Science 1985; 43:38.

Effect of dextran on mechanical fragility of rat red blood cells. Georgia Academy Science, Carrollton, GA, Apr 1985.
Published abstract: Georgia J Science 1985; 43:38.

Pluronic polyols and rat blood cell membrane fragility. Fed Am Soc Experi Biology, Anaheim, CA, Apr 1985.
Published abstract: Federal Proc 1985; 44:1043.

Serum gastrin, cholesterol and triglyceride levels in the cobalt chloride treated rat. 67th Annual Meeting Endocrine Soc, Baltimore, MD, 19-21 Jun 1985.

The influence of cobalt ion concentration on rat red blood cell mechanical fragility. Annual Conference Georgia Nutrition Council, Atlanta, GA, 21-22 Mar 1985.

Serum lipoprotein disassociation by pluronic F-127. Annual Conference Georgia Nutrition Council, Atlanta, GA, 21-22 Mar 1985.

Cholesterol and triglyceride values in the cobalt chloride treated rat. Annual Conference Georgia Nutrition Council, Atlanta, GA, 21-22 Mar 1985.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 82-20 Status: Ongoing
 Title: Correlations Between Extent of Patient Involvement and Effectiveness of Published Behavioral Treatments of Hypertension.

Start Date: Nov 81	Est Comp Date:	
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MS	Facility: Eisenhower Army Medical Center	
Dept/Svc: Clinical Investigation	Associate Investigators:	
Key Words: Patient involvement Hypertension Behavioral treatment		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether the extent of patient in behavioral treatment of hypertension affects treatment success.

Technical Approach: The methods and results sections of all published articles on behavioral treatment of hypertension containing sufficient detail to permit analysis are sorted into "blind" booklets for rating. Physician and PhD groups are asked to "blind" rate each method and result section without knowing which are related to each other.

Progress: Data gathering for this project has been done for virtually a year but analysis has been very slow due to the lack of adequate statistical support. Eisenhower has approved a contract with the Medical College of Georgia to provide statistical analysis support for those projects beyond the capabilities of the medical center's resources. As soon as this contract goes into effect, we will complete analysis of the data. This project will be completed when the data analysis is done.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 82-43 Status: Ongoing
 Title: Development of an Animal Model of Phantom Pain.

Start Date:		Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators: Mrs. Crystal Sherman, M.S.
Key Words: Phantom pain Animal model Rat		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$3,200	Periodic Review Results
Study Objective: To develop an animal model of phantom pain.		

Technical Approach: Rats are trained to respond to gentle, harmless, shocks by pressing different levers depending on where along the foreleg the shock is given in order to receive a milk reward. After training is successful, the foreleg is amputated by a combined veterinary-orthopedic surgery team while the animal is under anesthesia. Following recovery, the shocks are presented to the remaining portion of the foreleg. The number of responses to stimulation of areas no longer present are compared with the previous number of incorrect responses.

Progress: Due to lack of technical support, progress on this project remains almost nil. Over the summer, a volunteer spent one day a week training the ten rats available for the project. They cannot recognize the relationship between receiving a sip of sweet milk and the cues required to participate in the study. We will attempt to assign a technician one-third time to this project starting in December 1985. If this technician cannot be adequately freed up to carry out the study consistently, the study will be terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 83-8 Status: Ongoing
 Title: Effects of the Psychophysiologic Recording Environment on Stress
 Labile Physiologic Systems.

Start Date:		Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators: Jack A. Horner, B.S.
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jan 85 Review Results Continue

Study Objective: 1) To determine the placebo value of an electronic device used with several physiologic dysfunctions in which stress is the major independent variable underlying temporal patterns of severity. 2) To evaluate habituation to the environment through repeated recording of the parameters over time.

Technical Approach: Forty, newly diagnosed, unmedicated borderline hypertensives (BPs in range of 140/90 - 160/110) and 40 chronic tension headache patients will participate in the study. All participants will be basically free of other disorders at the start of the study and will be dropped from the study if need for medication occurs, or other problems develop.

Progress: None due to no available technical support. If sufficient technical support to at least begin this project cannot be freed up this year, it will be terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 83-37 Status: Ongoing
 Title: Determination of Glomerular and Nonglomerular Bleeding by Examination of RBC's in Urine Using Scanning Electron Microscope (SEM).

Start Date: Jul 83		Est Comp Date:
Principal Investigator(s) Jack A. Horner James A. Hasbargen, M.D., MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words: Electron microscopy, Kidney biopsy, Glomerular bleeding		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: It has recently been suggested that red blood cells (RBC) from glomerular causes appear different than RBC from nonglomerular causes. Our goal is twofold: a) to insure the differences are not secondary to osmotic or fixation artifacts, and b) to quantitate and confirm the prior observations.

Technical Approach: This study consists of two parts, a study of urine bound red blood cell (RBC) morphological changes as a result of urine parameters (e.g., holding time, pH, osmolarity, etc.), and a characterization of RBC morphology in urine from patients with hematuria both with and without glomerular bleeding. In the first part, normal peripheral blood is placed in urines of varying pH, osmolarity, etc., for varying times. The samples are then spun down, fixed in glutaraldehyde, dehydrated, filtered onto nucleopore 0.2) filters, critical point dried, gold sputtered, and examined in the scanning electron microscope. A minimum of 100 RBC's from each sample will be examined, then morphology noted, and representative cells photographed to determine the effect of urine parameters on RBC morphology. In the second part the same processing regimen is employed on patient urine samples and the resultant RBC morphology recorded.

Progress: The departure of one of the principal investigators (Hasbargen) has delayed the timely completion of this study. To date we have shown a 100% correlation between the "torroidial" RBC morphology and glomerular bleeding as confirmed by renal biopsy. Additional urine specimens will be submitted by Dr. Hasbargen from his new duty station.

Detail Summary Sheet

Date: 17 Oct 85		Prot No.: 84-5		Status: Completed	
Title: Chronic Osteomyelitis Animal Model With <u>Staphylococcus aureus</u> and <u>Bacteroides fragilis</u> .					
Start Date: Nov 83			Est Comp Date:		
Principal Investigator(s) Richard W. Harris, MAJ, MSC			Facility: Eisenhower Army Medical Center and VAMC Augusta		
Dept/Svc: Clinical Investigation			Associate Investigators: J. Peter Rissing, M.D.		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To develop a model of chronic osteomyelitis using S. aureus and B. fragilis and to study the pathology of the disease and treatment.

Technical Approach: Rat tibiae were aseptically exposed under an anesthesia, a small hole was drilled in the bone and injected with 5 μ l of either Bacteroides fragilis, staphylococcus aureus or both organisms, and the wound closed with bone wax. Animals were maintained up to 70 days and evaluated for gross, pathology, bacterial colony counts and percent of bone involvement.

Progress: A tibial osteomyelitis model was used to examine synergy between S. aureus and B. fragilis without sclerosing agent. S. aureus (52/52A/80) produced osteomyelitis in 7 of 8 rats at inocula as low as 10 cfu. The ID50 was 10. B. fragilis (ATCC 23745) produced osteomyelitis in 0 of 6 and 3 of 9 rats at inocula of 10 and 10, respectively. The ID50 was 10. S. aureus inocula of only 10 cfu produced mean S. aureus tibial cfu of 10 at 21 days when 10 cfu B. fragilis were added to the inocula; none were seen without B. fragilis. Synergy was correlated to B. fragilis inoculum size. However, B. fragilis augmentation of S. aureus counts decreased when S. aureus inocula exceeded 10. Roentgenographic bone destruction and gross tibial pathology were related to presence of S. aureus in monomicrobially infected rats. The presence of B. fragilis, in either monomicrobial or bimicrobially challenged rats, contributed less to observed bone destruction or gross pathology in the period observed.

Rissing JP, Buxton TB, Harris RW, Shockley RK: Bimicrobial experimental S. aureus osteomyelitis in rats: Facilitation of infection by B. fragilis. Presented at 24th ICAAC, October 1984.

Rissing JP, Buxton TB, Horner JA, Shockley RK, Fisher JF, Harris RW: Synergism between B. fragilis and S. aureus in experimental tibial osteomyelitis. Submitted to J Infectious Dis.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-50		Status: Ongoing	
Title: A Scanning and Transmission Electron Microscopic Study of the Effects of Cadmium on the Early Developmental Components of the Craniofacial Region of the Hamster Embryo					
Start Date: Jul 84			Est Comp Date: July 86		
Principal Investigator(s) Jack A. Horner, B.S. Thomas F. Gale, PhD			Facility: Eisenhower Army Medical Center Medical College of Georgia		
Dept/Svc: Clinical Investigation Anatomy Dept, MCG			Associate Investigators:		
Key Words: Electron microscopy, Cadmium, Teratology					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To utilize electron microscopy to compare the fine structural features of the component tissues of 13 different regions of the face at selected timed-intervals during the early development of the craniofacial region in cadmium-exposed vs control hamster embryos.

Technial Approach: Cadmium sulfate solution is injected (IV) into timed pregnant golden hamsters on the eighth gestation day (8 AM) and embryos are collected at selected times during the period of early facial development, i.e., day 8 at 6PM; day 9 at 8AM; day 10 at 8 AM; day 10 at 6PM; day 11 at 8 AM. The embryos are fixed, dehydrated by critical point drying, coated with gold, and examined and photographed in the scanning electron microscope. Comparisons between embryos from the control (sham-injected) and experimental (cadmium-injected) pregnant hamsters will reveal the teratogenic effects of cadmium on the developing embryonic face. The comparisons will be both qualitative and quantitative. Collection of the quantitative data on surface area measurements will be accomplished by utilization of a computer interfaced morphometric digitometer system.

Progress: The qualitative and quantitative study of the 121 embryos (57 controls + 64 cadmium-exposed) collected at gestation day 10 at 8AM has been completed. The data obtained from this phase of the project presents new information regarding the relative surface area contribution for each of the 13 regions of the face which were measured at a time midway during the period of facial prominence formation. Further, this study demonstrates that the specific cadmium treatment of the pregnant hamster utilized here results in significant changes in both the qualitative appearance of the face and the surface area measurements of the 13 facial regions in the day 10 at 8AM embryos. Specifically this cadmium treatment produced statistically significant reductions in the surface area measurements of the frontonasal, medial and lateral nasal and maxillary prominences as well as a statistically significant increase in the surface area of that portion of the frontonasal prominence between the two medial nasal prominences. The surface area of the nasal pit region of the face was little affected by the cadmium treatment. This data obtained in this first phase of this study is consistent with the

hypothesis tested i.e., the occurrence of cadmium-induced facial malformations involved a disruption of the normal formation and/or fusion of one or more of the facial prominences. All of the scanning electron micrographs and quantitative data has been collected and tabulated for two additional embryo collection times i.e., day 10 at 6PM (131 embryos = 55 controls + 76 experimentals) and day 11 at 8AM (132 embryos = 73 controls + 59 experimentals). The statistical analysis of this data is currently in progress. Data collection and analysis for the day 8 at 6PM and day 9 at 8AM embryo collections times remains to be accomplished.

Gale TF, Horner JA: Effects of cadmium on early facial development in hamsters: Surface area measurements. Presented Southeast Electron Microscopy Society, Annual Meeting May 1985. Published in proceedings for this meeting.

Gale TF, Horner JA: Effect of cadmium on the facial prominences of hamster embryos. Preliminary findings. Presented at Teratology Society Meeting July 1985. Published in J Teratology 1985; 31:52-53A.

Gale TF, Horner JA: The effect of cadmium on the early development of the face in the hamster. I. Surface area measurements of 10-8AM embryos. Submitted to J Environmental Research.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 85-18		Status: Ongoing	
Title: Ultrstructural Alterations to Human Skin Stored at 40C in Nutrient Medium and Saline.					
Start Date: Apr 85			Est Comp Date:		
Principal Investigator(s) S. Randolph May, PhD Jack A. Horner			Facility: Eisenhower Army Medical Center		
Dept/Svc: Clinical Investigation			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To determine the structural nature of the degradation of human skin stored at 40C in Eagle's Minimal Essential Medium, with particular reference to the vascular elements.					

Technical Approach:

Progress: Implementation of this study was deferred until FY 86 due to the loss of technical support in Dr. May's laboratory. Initial samples will be obtained during first quarter FY 86.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 85-31		Status: Ongoing	
Title: Effect of Sodium Salicylate on Nonenzymatic Glucosylation of Human Serum Albumin.					
Start Date: Jul 85			Est Comp Date:		
Principal Investigator(s) Kulthoum A. Mereish, CPT, MS			Facility: Eisenhower Army Medical Center		
Dept/Svc: Clinical Investigation			Associate Investigators:		
Key Words: Sodium salicylate, Human serum albumin, Glucosylated albumin					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To determine the effect of salicylate on the nonenzymatic reaction, the glucosylation of human serum albumin <u>in vitro</u> .					

Technical Approach: Human serum albumin will be incubated for 90 minutes with different levels of sodium salicylates. Glucose concentration that simulate normal and diabetic levels will be added to salicylate-albumin and incubated at 37°C for several days. At the end of incubation period, free salicylate and glucose will be dialyzed and the amount of glucosylated albumin will be determined.

Progress: Preliminary data indicates a decrease in the amount of glucosylated albumin at 1.0-7.5 µg/ml.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 83-32 Status: Ongoing
 Title: Mandibular Lingual Vertical Releasing Incisions.

Start Date: Aug 83		Est Comp Date:
Principal Investigator(s) William M. Ekvall, MAJ, DC		Facility: Eisenhower Army Medical Center
Dept/Svc: Dental Activity		Associate Investigators:
Key Words:		
Accumulative MEDCASF Cost:	Est Accumulative OMA Cost:	Periodic Jul 85 Review Results Continue

Study Objective: Compare the healing and post-operative sequelae of two different types of incisions used in periodontal surgery.

Technical Approach: Each patient in the study will have each of the two types of incisions performed in his mouth, one on each side of the mandible. Progress of healing will be followed with a symptom data log and clinical photographs.

Number of subjects enrolled to date: 10
 Number of subjects enrolled for reporting period: 6

No adverse complications have occurred.

Progress: One patient is currently awaiting initiation of surgery.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-9		Status: Ongoing	
Title: The Role of Excessive Sympathetic Stimulation on Penicillin Blood Levels After P.O. Administration					
Start Date: Jan 84			Est Comp Date:		
Principal Investigator(s) Lavelle Ford, MAJ, DC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Dentistry-Clinical Investigation			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic May 85 Review Results Continue	

Study Objective: To determine the effects, if any, of nervousness and apprehension on the absorption and subsequent blood levels of antibiotics given by mouth. Many patients have heart defects or conditions that require that they receive antibiotics before they undergo dental procedures or other surgical therapy. These antibiotics can be given orally. This study will attempt to determine if nervousness affects the rate at which these antibiotics enter the blood stream.

Technical Approach: Healthy volunteers who have twice previously been given penicillin and are negative by allergy skin test will be chosen for the study. Two grams of penicillin-V will be taken orally the morning of surgery and a peripheral line with a heparin lock started. Samples are taken at time 0, 30 minutes, 60 minutes, 90 minutes, and 120 minutes after closing. One 5 ml sample for a red-topped tube will be drawn for an EDTA tube. Serum will be analyzed by bioassay for penicillin concentration. Plasma will be evaluated by HPLC for catecholamine levels and by RIA for ACTH concentrations. All patients will fill out a self-evaluation stress questionnaire prior to surgery.

Number of patients enrolled to date: 18
Number of patients for reporting period: 5

Progress: Plasma has been frozen for later processing for catecholamines and ACTH. The patient penicillin concentration means are as follows: 30 min, 13.6±3.0 mg/ml; 60 min, 22.3±3.1 mg/ml; 90 min, 14.5±1.8 mg/ml; and 120 min, 9.5±1.2 mg/ml. Controls and patient serum penicillin concentrations, ACTH, and catecholamine concentrations and self-evaluation questionnaires will be compared and evaluated.

Detail Summary Sheet

Date: 18 Oct 85 Prot No.: 84-44 Status: Completed
 Title: Healing Following Temporomandibular Joint Meniscus Surgery in Rabbits.

Start Date: Sep 84	Est Comp Date: May 85
Principal Investigator(s) William P. Mills, Jr., MAJ, DC	Facility: Eisenhower Army Medical Center
Dept/Svc: Dental Activity Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To examine the histological patterns of healing following meniscus plication surgery with and without fascial/dermal grafting of the joint meniscus in the adult rabbit.

Technical Approach: The deep fascia will be incised over the joint, a meniscus plication will be performed. After irrigation, the capsule and subcutaneous tissues will be closed with sutures and the overlying soft tissues approximated with wound clips. Identical procedures will be carried out on the opposite side except fascial/dermal grafts will be placed overlying 2mm surgical defects created in the posterolateral aspect of the disk. Ten white laboratory rabbits will be required.

Progress: The meniscus plication surgery with and without fascial/dermal grafting of the joint meniscus has been performed in all eight experimental animals. Post-surgical healing periods of two weeks, one month, three months and six months have elapsed. In addition, all ten white laboratory rabbits including two control animals have been sacrificed, and the temporomandibular joints bilaterally have been excised and placed in formalin. At present the joints are to be decalcified, embedded, sectioned, mounted and stained prior to histological examination.

Detail Summary Sheet

Date: 17 Oct 85		Prot No.: 85-10		Status: Ongoing	
Title: Masseter Muscle Silent Period in Patients with Internal Derangements of the Temporomandibular Joint Before and After TMJ Surgery.					
Start Date: Jan 85			Est Comp Date:		
Principal Investigator(s) Edmund A. Casella, MAJ, DC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Dentistry, Clinical Investigation			Associate Investigators: Richard A. Sherman, CPT, MS Jerry Schwartz, MAJ, DC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To assess the usefulness of EMG silent period measurements when evaluating TMJ patients for surgery.					

Technical Approach: The subjects will be those patients scheduled for TMJ surgery due to internal derangements of their joint. No medications or invasive techniques will be employed that are not routinely used for this surgical procedure. The EMG masseter muscle silent period will be recorded before surgery, after recovery from surgery, and during follow-ups. EMG results will be correlated with pain intensity and jaw function measurements.

Number of subjects enrolled to date: 12

Progress: Twelve patients have been recorded to date before and after surgery. The data have not been evaluated because initial follow-ups have not been done yet.

Detail Summary Sheet

Date: 1 Oct 85	Prot No.: 85-16	Status: Ongoing
Title: Long Term Effectiveness of Sodium Fluoride on Tooth Hypersensitivity With and Without Iontophoresis.		
Start Date: Apr 85	Est Comp Date: Mar 86	
Principal Investigator(s) Michael McQuade, COL, DC	Facility: Dental Activity	
Dept/Svc: Dentistry/Periodontics	Associate Investigators: David Kern, MAJ, DC	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To enhance the effectiveness of current treatment modalities for hypersensitive teeth.

Technical Approach: The iontophoresor will be connected to the teeth in both treatment groups, but will be activated in only one. This procedure will help to blind the patient to the procedure. Mechanical and thermal stimulation will be used to quantitate a patient response and assess the efficacy of the treatment modalities.

Progress: For the past four months we have had difficulty obtaining an adjustable (Yeaple) probe; however, this problem has been solved. We are currently negotiating a lease arrangement for this instrument and expect to have it on site within sixty days. Obviously, no patients have been, as yet, entered into this study. All other parameters of this study remain intact and the estimated date of completion remains the same.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 85-17 Status: Ongoing
 Title: The Use of Ultrasound for Diagnosis in Periodontal Bone Morphology.

Start Date: Apr 85	Est Comp Date: Mar 86
Principal Investigator(s) Miguel E. Palou, MAJ, DC	Facility: Dental Activity
Dept/Svc: Dentistry/Periodontics	Associate Investigators: Michael J. McQuade, COL, DC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To provide more accurate diagnostic measurements for periodontal bone morphology.

Technical Approach: The project consists of measuring the alveolar bone height from the free gingival margin. This measurement is done with the ultrasound machine Ocu-Scan 400 located at the Ophthalmology Clinic at Eisenhower. Population: patients scheduled to undergo periodontal surgery. At the time of surgery, with the aid of an acrylic stent, the bone height is measured once the mucoperiodontal flap has been resected. The ultrasound measurement and the clinical measurement will then be compared for accuracy.

Subjects enrolled to date: two.

Progress: At present two patients with seven potential areas of study have been enrolled. On both patients, measurements with ultrasound machine were obtained. On one of the patients one surgical intervention was performed and clinical measurements obtained. The data is still not available for comparison.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 85-22		Status: Ongoing	
Title: The Effect of Tobacco Smoke on the Attachment of Human Gingival Fibroblasts to Root Surfaces in vitro.					
Start Date: May 1985			Est Comp Date: May 1986		
Principal Investigator(s) Leslie A. Raulin, DMD, MAJ, DC			Facility: Dental Activity, DDEAMC		
Dept/Svc: Dentistry Clinical Investigation			Associate Investigators: Michael McQuade, DDS, COL, DC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To investigate the effect of tobacco smoke on the attachment of human gingival fibroblasts to non-diseased human root surfaces.					

Technical Approach: In vitro study using extracted tooth roots, purchased fibroblasts, and nicotine in culture media. Study being conducted at Clinical Investigation Lab with assistance of their personnel.

Progress: Roots have been procured and prepared. Supplies have been ordered. Cells have been ordered. Pilot study will begin this week.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 83-36 Status: Completed
 Title: The Interrelationship of Pregnancy and Fitness.

Start Date: Sep 83		Est Comp Date: Jan 85
Principal Investigator(s) Jeannette E. South-Paul, M.D., MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Family Practice		Associate Investigators:
Key Words: Exercise, Pregnancy, Fitness		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jan 85 Review Results Continue

Study Objective: 1) To determine whether pregnancy causes a decrease in physical fitness as measured by maximum oxygen consumption between the second and third trimesters; and 2) to assess whether the maintenance of a regular exercise program during the second half of pregnancy will affect fitness and the outcome of the pregnancy.

Technical Approach: Graded exercise tests performed two times at 20 and 30 weeks gestation on both an exercise and a control group. Supervised exercise in PT Dept for exercise group from 20 weeks gestation on.

Subjects enrolled to date: 21
 Subjects enrolled for reporting period: 1

Progress: The protocol is completed with all participants delivered. One adverse outcome in exercise group (reported earlier), stillbirth - not thought due to program. Data has yet to be completely evaluated statistically.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 85-26		Status: Ongoing	
Title: The Interrelationship of Exercise and Fitness During Pregnancy and the Postpartum Period.					
Start Date: Aug 85			Est Comp Date:		
Principal Investigator(s) Jeannette E. South-Paul, M.D., MAJ, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Family Practice/Physical Therapy/ Occupational Therapy			Associate Investigators: Gaetano G. Scotece, CPT, SP Paula J. Raevsky, CPT, SP		
Key Words: Exercise, Fitness, Pregnancy, Postpartum					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To assess whether the maintenance of an organized exercise program during the second half of pregnancy with result in improved fitness in the postpartum period. This study is a prospective trial of active duty and dependent women, ages 18 to 35, whose pregnancies are uncomplicated.

Technical Approach: Randomly assigned exercise and control groups will be given a baseline fitness test at 16 weeks gestation and will have this test repeated at 32 weeks gestation and six weeks postpartum. The program for the exercise group involves aerobics (aquatics), stretching exercises and non-water aerobic exercises.

Number of subjects enrolled to date: 17.

Progress: There have been some difficulties in obtaining support from unit commanders to release active duty pregnant women to participate in the program. There have been no problems among those who do participate.

Detail Summary Sheet

Date: 17 Oct 85		Prot No.: 78-38		Status: Ongoing	
Title: Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Part I. Human Immunologic Reactivity to Fire Ant Antigens. BB IND 1452					
Start Date: Feb 85			Est Comp Date:		
Principal Investigator(s) Antonio L. Bunker-Solaz, LTC, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Medicine/Immunology			Associate Investigators: Robert B. Rhoades, M.D., Medical College of Georgia Chester T. Stafford, M.C., Medical College of Georgia		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Mar 85 Review Results Continue	

Study Objective: 1) To compare the skin test reactivity of fire ant venom and its components with whole body extracts (WBE) of fire ants in patients allergic to stings of the imported fire ant. 2) To compare skin test reactivity with in vitro immunologic studies (RAST and Histamine release). 3) To determine the pretreatment immunologic status of fire ant sensitive patients prior to their participation in studies comparing the relative efficacy of immunotherapy with fire ant venom (Part III protocol) versus whole body extracts (Part II protocol) versus placebo, pending DA approval. Part IV on separate summary sheet.

Technical Approach: The following imported fire ant (S. invicta) antigens have been prepared:

- 1) 96-1 ml vials of freeze-dried whole venom (1:1000 w/v after reconstitution).
- 2) 146-1 ml vials of freeze-dried front end (FE) body segment extract (1:10 w/v after reconstitution).
- 3) 145-1 ml vials of freeze-dried anterior end (AE) body segment extract (1:10 w/v after reconstitution).

Number of subjects enrolled for reporting period: 3

Progress: Approval by the FDA obtained in February 1985 for skin testing and human clinical studies.

Human clinical studies initiated:

- a. Freeze-dried whole venom, front end (FE), and abdominal end (AE) were reconstituted.
- b. These as well as commercial whole body antigens have been used for skin test comparison studies on the three volunteers who so far have entered the study.
- c. No adverse reactions have been noted.
- d. Blood obtained and in vitro immunological studies (RAST and histamine release) have been set up.

"Seasonal variation in antigens for the imported fire ant Solenopsis invicta" submitted to J Allergy Clin Immunol.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 83-22		Status: Ongoing	
Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma.					
Start Date: Feb 85			Est Comp Date:		
Principal Investigator(s) Marshall A. Guill, M.D., LTC, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Medicine/Dermatology			Associate Investigators: James K. Aton, Jr., M.D., COL, MC John R. Cook, M.D., LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Mar 85 Review Results Continue	

Study Objective: To evaluate the effectiveness of low dosage levels of isotretinoin in reducing the incidence of basal cell carcinomas in a high risk population. To examine possible side effects associated with long term administration of low doses of isotretinoin.

Technical Approach: Patients with two or more basal cell carcinomas (BCC) in the past five years are eligible for inclusion in the study. They must be between the ages of 40 and 75 and incapable of bearing children. After a thorough physical examination, including basic laboratory data, participants are randomized to either the treatment group or the placebo group. The medication is provided by the National Cancer Institute and is double-blinded. Participants take medication for 36 months, continuing to be followed for the following 24 months for a total of 60 months in the study. We hope to enroll a total of 150 patients during the 18-month enrollment period.

Funding is being provided by the NCI through an interagency agreement between DDEAMC and the NCI. Funding for FY 85 totaled \$37,156.00. Utilizing these funds, we hired Ms. Pat Challenger in January 1985 and after an orientation meeting at Bethesda with NCI officials, we started to enroll patients into the study.

Progress: We have sent questionnaires and information brochures to 193 patients. Of these, we have screened 65 patients. Of those screened, 51 were eligible to enter the study. We have enrolled 50 patients in the study to date. We have accrued patients at a very acceptable rate; however, I anticipate that our accrual rate will slow down as we exhaust patients with multiple basal cells who were waiting to be enrolled.

We have experienced a few adverse reactions which may be related to the study medication. One patient developed an elevated serum triglyceride level (338) and the study medication was discontinued. After six weeks off medications, her triglyceride level was 140. This may or may not have been related to study medication (N=0-210). Other adverse reactions which may be related to study medication involve dry, chapped lips and drying of nasal and/or ocular mucosa. In some cases, these reactions have been managed with lubricants. In other cases, dose modifications have been necessary. In only the one case cited, has the study medication been discontinued due to adverse reactions. Another patient decided to stop taking the medicine four days after beginning. We are still following this patient.

Detail Summary Sheet

Date: 5 Jun 85 Prot No.: 84-51 Status: Completed
 Title: DIPLOS-04 Pacemaker Investigation

Start Date: Jun 84		Est Comp Date: Apr 85
Principal Investigator(s) John D. Rathbun, M.D., MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic May 85 Review Results Completed

Study Objective: The DIPLOS-04 protocol was a clinical validation study utilized in the BIOTRONIK DIPLOS-04 Dual Chamber Pulse Generator. This study was being conducted under an investigational device exemption and consisted of 20 centers and 20 investigators.

Technical Approach: The study was designed using patients who required use of dual chamber DDD pacing. The pacemakers were inserted for the Cardiology Service utilizing the Cardiac Catheterization Laboratory, Cardiac Catheterization Laboratory Technologists and the Cardiology Service. The funding was provided by the usual sources for the implantation of pacemakers.

Number of subjects enrolled to date: 6.
 Number of subjects enrolled for the reporting period: 3

There have been no significant adverse reactions. There has been one case of pocket twitch which is non-pacemaker related.

Progress: The total number of DIPLOS-04 generators currently implanted nation-wide has exceeded 100. the overall results of this study have indicated that the DIPLOS-04 dual chamber generator is a sturdy pacemaker with no basic dangers or nuisance flaws. As for pacemaker-mediated tachycardia, this has not been observed as a complication secondary to the program ability of the atrial refractory period. In addition, the AV-delay fallback mechanism has allowed increased sinus node activity and fast atrial rates with flexibility in the program ability of the AV delay.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 85-11		Status: Terminated	
Title: Comparative Study of Oral RU 965 and Erythromycin Ethylsuccinate in the Treatment of Patients with Infections Caused by Susceptible Bacteria.					
Start Date:			Est Comp Date:		
Principal Investigator(s) D. Baxter Craig, MAJ, MC Robert E. Morrison, COL, MC J. Peter Rissing, M.D.			Facility: Eisenhower Army Medical Center Medical College of Georgia		
Dept/Svc: Medicine/Infectious Disease			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To compare the safety, efficacy, and tolerance of RU 965 with those of erythromycin ethylsuccinate in the treatment of adult patients with infections due to susceptible pathogens.					

Technical Approach:

Progress: Due to changes in the experimental design requested by the pharmaceutical company which the investigator felt would make the study invalid, the study was terminated prior to the enrolling of any patients or the distribution of study drug to Eisenhower Army Medical Center.

Detail Summary Sheet

Date: 1 Nov 85		Prot No.: 85-13		Status: Ongoing	
Title: Protracted Venous Infusion of 5 Fluorouracil with Intermittent Cis-Platinum: A Phase II Trial to Test for Synergistic Anti-Neoplastic Activity in Metastatic Colon Cancer.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Richard P. Mansour, MAJ, MC Marcus L. Troxell, CPT, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators: Steven A. Madden, MAJ, MC Jannet M. Schoch, MAJ, ANC Mr. Lyle M. Glascock		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: 1) To study the efficacy of prolonged (28 day) 5 fluorouracil infusion with intermittent cis-platinum in metastatic colon cancer. 2) To reduce the need for hospital confinement for chemotherapy administration.					

Technical Approach:

Number of subjects enrolled to date: 2

Progress: All elements are in place to carry out this study. One patient received one cycle of chemotherapy for metastatic colon cancer and had an unexpected death from a ruptured aortic aneurysm which was completely unrelated to his cancer or his chemotherapy. A second patient was entered in the study and received three cycles of chemotherapy. His disease remained stable, however, due to lack of an objective regression in tumor, this patient was taken off study. We are planning to accrue more patients as they become available.

Detail Summary Sheet

Date: 29 Oct 85		Prot No.: 85-14		Status: Ongoing	
Title: Protracted Venous Infusion of 5 Fluorouracil with Intermittent Cis-Platinum: A Phase II Trial to Test for Synergistic Anti-Neoplastic Activity in Metastatic Non-Small Cell Lung Cancer.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Marcus L. Troxell, CPT, MC Richard P. Mansour, MAJ, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators: Steven A. Madden, MAJ, MC Jannet M. Schoch, MAJ, ANC Mr. Lyle M. Glascock		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: This study proposes the use of protracted constant venous infusion of 5FU for 28 consecutive days with intermittent administration of cis-platinum as therapy for metastatic non-small cell lung cancer. Response rates and survival will hopefully be increased while toxicity from therapy is minimized. Morbidity from the procedure is expected to be minimal. The silastic centrastil and intrasil catheters used in this study are known to be associated with fewer infectious and thrombotic complications than the polyvinyl chloride catheters used in Lokich's studies.

Technical Approach: This is a nonrandomized, single-arm phase II study designed to assess response rates of patients with non-small cell lung cancer to protracted infusion 5-FU and intermittent Cis-platinum. The study is being conducted by the staff and ancillary personnel in the Oncology Clinic with no other personnel being required. Ten Cormed Pumps were purchased during the last year at a cost of \$1200 each to accommodate the patients on this and the colon cancer study. These pumps are also in use for other patients who are not on protocol. Ten patients have been enrolled on the lung cancer study to date, nine of these were enrolled for the reporting period ending 30 September 85. Protracted infusion 5-FU has been generally well tolerated with a few patients developing mild to moderate mucositis requiring a one step dose reduction. The intermittent Cis-platinum produced the expected side effects of moderate to severe nausea and vomiting which was controlled by high dose Metaclopramide on $\frac{1}{2}$ to $\frac{2}{3}$ of the patients. Approximately $\frac{1}{2}$ of the patients are able to receive their Cis-platinum as an outpatient in the clinic. The tunnel Centrastil Elastic Catheters have been problem-free. One catheter was exchanged in a protocol patient because of a cracked hub. No other patient on protocol has had problems related to his subclavian catheter.

Progress: To date, no patient with metastatic non-small cell lung cancer enrolled on the protracted 5-FU infusion intermittent Cis-platinum chemotherapy has responded to treatment. All patients enrolled so far have had disease progression and have been removed from the study. Current plans are to enroll a total of approximately 12 to 14 patients on the study. If no objective responses are seen, the study will be closed and the results submitted for publication. A new study which may be considered following conclusion of this would be protracted infusion velban with intermittent Cis-platinum in patients with metastatic non-small cell lung cancer.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 85-23		Status: Ongoing	
Title: Effect of Ketoconazole Therapy on the Susceptibility of Enteric Fungi to Amphotericin B and Ketoconazole.					
Start Date: June 1985			Est Comp Date: June 1986		
Principal Investigator(s) Ruth Marie E. Fincher, MD			Facility: Eisenhower Army Medical Center, Medical College of GA		
Dept/Svc: Medicine/Dermatology			Associate Investigators: Marshall Guill, MD, LTC, MC John F. Fisher, MD		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To ascertain ketoconazole and AMB susceptibility patterns of stool fungal isolates in patients prior to and following treatment with ketoconazole.

Technical Approach: Stool specimens are obtained before and after treatment with ketoconazole. These are then cultured and fungal isolates are tested for amphotericin B susceptibility.

No excess Eisenhower manpower is required for the study. All cultures and sensitivity tests are done at the Medical College Laboratories.

No funding is required.

We have enrolled eight subjects to date. Of these, two have voluntarily withdrawn by refusing to produce a second stool specimen. All of the patients enrolled thus far elected to take ketoconazole for severe tinea versicolor infection. After deciding to use this form of therapy, they were questioned as to their willingness to participate in the study. We hope to enroll approximately 15 more persons in the study.

We have had no adverse reactions as there is essentially no risk to the patient in providing a stool specimen, only inconvenience. It is presumed that the two persons who have dropped out of the study thus far did so because it was not convenient to provide a second stool specimen.

Progress: We have been successful in culturing yeast from the stools of two patients, both before and after ketoconazole treatment. We have not yet begun our susceptibility studies as it will be easier to do these in a larger group. We feel we are accruing patients at a reasonable rate. Most of our patients are being treated with ketoconazole for tinea versicolor. This is not a first line therapy for tinea versicolor, and is only used in severe or recalcitrant cases.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 85-24		Status: Ongoing	
Title: Extravascular Penetration of Antimicrobial Agents in New Zealand White Rabbits.					
Start Date: June 1985			Est Comp Date: June 1986		
Principal Investigator(s) Robert E. Morrison, MD, COL, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Medicine Clinical Investigation			Associate Investigators: Kulthoum A. Mereish, CPT, MS		
Key Words: Antimicrobial agents Beta-lactam antibiotics					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost: 6,200		Periodic Review Results	

Study Objective: To examine new antimicrobial agents to determine the comparative ability to penetrate into intraperitoneal and subcutaneous extravascular compartments.

Technical Approach: Sterile plastic capsules will be implanted intraperitoneally and subcutaneously into New Zealand white rabbits. Six weeks following surgery, a three-day therapy will be initiated by i.p. injection to achieve equilibrium plasma levels. Drug profile in plasma and capsule will be monitored. Pharmacokinetic evaluation of drug plasma levels and drug capsule levels will be performed.

Progress: HPLC analysis of clavulanic and amoxicillin in rabbit serum was developed. The method will be submitted for publication in J Pharm Sci.

Detail Summary Sheet

Date: 16 Oct 85 Prot No.: 85-38 Status: Ongoing
 Title: Comparison of rehabilitation Benefits of Supervised Hospital-Based Exercise and Unsupervised At-Home Exercise After Myocardial Infarction.

Start Date: Oct 85		Est Comp Date:
Principal Investigator(s) Carolyn G. Bernheim, MCN, CPT, ANC Gaetano G. Scotece, RPT, CPT, SP		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology Surgery/Physical Therapy		Associate Investigators: James Jenkins, Jr., MD, CPT, MC Kenneth A. Kaplin, MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the rehabilitation benefits of supervised hospital based exercise and unsupervised at home exercise after MI. This study is a prospective clinical trial of active duty, dependent and retired men and women, age 30 to 70, who have sustained a MI.

Technical Approach:

Progress: Locally approved late Sep 85, not yet implemented.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 82-3 Status: Closed
 Title: SWOG 7823/24/25/26 ROAP-AdOAP in Acute Leukemia, Phase III.

Start Date:	Est Comp Date:	
Principal Investigator(s)	Facility:	
Steven A. Madden, M.D., MAJ, MC	Eisenhower Army Medical Center	
Dept/Svc:	Associate Investigators:	
Medicine/Hematology-Oncology		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To compare the efficacy of the 4-drug combination chemotherapy regimen, ROAP (Rubidazone, vincristine, arabinosyl cytosine, and prednisone) to AdOAP (the same combination using Adriamycin in place of Rubidazone) in adult acute leukemia, as determined by remission rate, remission duration and survival. 2) To determine the comparative toxicity of these regimens. 3) To determine whether late intensification therapy at nine months after complete remission will improve long-term, disease-free survival. 4) To determine whether immunotherapy using levamisole for six months after 12 months of complete remission on chemotherapy improves disease-free survival. 5) To determine the effects of intrathecal Ara-C on the incidence of CNS leukemia. 6) To determine reproducibility of the FAB/histologic classification and correlation to response to therapy in 200 consecutive cases of acute leukemia. 7) To study the effects of intensive supportive care in the management of acute leukemia.

Technical Approach: All patients over 15 with a diagnosis of acute leukemia who have not received extensive therapy (defined as more than one course of any other chemotherapeutic agent or combination of agents) will be eligible for this study. The diagnosis of acute leukemia will be made on bone marrow smear, clot section and/or biopsy. An absolute infiltrate of 50% leukemic cells or greater is required.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 82-4 Status: Closed
 Title: SWOG 8001, Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III.

Start Date:		Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To evaluate the effectiveness as determined by the complete remission rate of the L10 protocol using Vincristine, Prednisone and Adriamycin for induction, followed by intensive consolidation in the treatment of acute ALL. 2) To compare the effect on remission duration and survival of two maintenance regimens: the L10 "eradication" regimen vs cyclic therapy with POMP-COAP-OPAL. 3) To determine the reproducibility of the FAB histologic classification and correlation to response to therapy of ALL in adults.

Technical Approach: Patients are eligible with the diagnosis of acute lymphoblastic leukemia who satisfy the following criteria: A) Absolute infiltration of the marrow with >50% blasts; absolute infiltration is defined as the total blast cell percentage (%) multiplied by the bone marrow cellularity percentage divided by 100. B) If the absolute infiltrate is 30-49%, evidence of progressive disease prior to entering the study will be required. Therapy will follow the schema outlined in the protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 82-5 Status: Closed
 Title: SWOG 7827, Combined Modality Therapy for Breast Cancer, Phase III.

Start Date:		Est Comp Date:
Principal Investigator(s)		Facility:
Steven A. Madden, M.D., MAJ, MC		Eisenhower Army Medical Center
Dept/Svc:		Associate Investigators:
Medicine/Hematology-Oncology		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy. 2) To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using one versus two years of combination chemotherapy alone. 3) To compare the disease-free interval and recurrence rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy. 4) To compare the effects of these various adjunctive therapy programs upon the survival patterns of such patients. 5) To correlate the ER status with disease-free interval and survival.

Technical Approach: All patients must have had a radical of modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Patients with postoperative radiation therapy are eligible but will be randomized and evaluated separately. Therapy will follow the schema outlined in the protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 82-7 Status: Closed
 Title: SWOG 7808, Combined Modality Treatment for Stage III and IV Hodgkin's Disease MOPP #6, Phase III.

Start Date:	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To attempt to increase the complete remission rate induced with MOB-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a partial response at the end of six cycles of MPO-BAP. 2) To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when complete response has been induced with six cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Eligible patients must have a histological diagnosis of Hodgkin's which must be classified by the Lukes and Butler system. Therapy will follow the schema outlined in the protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 82-9		Status: Closed	
Title: SWOG 7804, Adjuvant Chemotherapy With 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs Surgery Alone for Patients With Locally Advanced Gastric Adenocarcinoma, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the efficacy of adjuvant chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-groups IB, IC and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach: Eligible patients must have localized lesions at least extending into the submucosa and involving any of the deeper layers with the maximum allowable penetration into but not through the serosa; localized lesions extending through serosa, with or without direct extension to contiguous structures; a lesion diffusely involving the wall of the stomach with or without metastases to immediately adjacent perigastric nodes or a localized lesion of any depth with metastases to perigastric nodes in the immediate vicinity; a localized or diffuse lesion with metastases to perigastric nodes distant from primary, e.g., greater curvature lesion with metastases to superior gastric nodes (Group II) on lesser curvature.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85	Prot No.: 82-10	Status: Closed
Title: SWOG 8006, Preoperative Reductive Chemotherapy for Stage III or IV Operable Epidermoid Carcinoma of the Oral Cavity, Oropharynx, Hypopharynx or Larynx, Phase III.		
Start Date: Jan 82	Est Comp Date:	
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: Eisenhower Army Medical Center	
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the length of remission, recurrence-rates, survival-rates, and pattern of recurrence for patients receiving therapy utilizing surgery and postoperative radiation vs combined therapy utilizing preoperative chemotherapy, surgery and postoperative radiation therapy in operable Stage III or IV epidermoid carcinoma of the head and neck.

Technical Approach: Patients with operable lesions will be randomized between two therapeutic programs: Arm I - combined therapy including surgery and postoperative radiation therapy; or Arm 2 - combination chemotherapy followed by surgery and radiation therapy. Patients randomized to the chemotherapy limb will receive three courses of chemotherapy consisting of cis-platinum, methotrexate, vincristine and bleomycin.

Progress: One patient enrolled. No reportable data.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-10		Status: Closed	
Title: SWOG 7984, Treatment of Chronic Stage CML With Pulse, Intermittent Busulfan Therapy With or Without Oral Vitamin-A, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Sutyd objective: To determine the efficacy of standard pulse, intermittent busulfan therapy plus oral vitamin A in prolonging the chronic phase of CML, and hence in prolonging survival.

Technical Approach: All patients with newly diagnosed chronic stage CML will be eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-11		Status: Closed	
Title: SWOG 7990, Intergroup Testicular Study (A cooperative study of Stage I and II testicular cancer of germ cell origin using Bleomycin, Vinblastine, Cis-Platinum.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To compare the disease-free survival and overall survival for surgery alone (with chemotherapy for relapsers) versus surgery plus early adjuvant chemotherapy in patients with resectable Stage II testicular cancer. 2) To register and follow patients with non-seminoma, non-choriocarcinoma Stage I testicular cancer, to define prognostic variables which may predict recurrence in this stage group. 3) To define the difference in disease-free rates and patterns of recurrence, based upon histologic subtypes and extent of disease on initial presentation. 4) To evaluate the role of marker substances such as: human chorionic gonadotrophin (BHCG), alpha-fetoprotein (AFP) and lactic dehydrogenase (LDH) in the early detection and management of recurrence in patients with Stage I and Stage II testicular carcinoma. 5) To evaluate the accuracy of lymphangiograms, CAT scans, and ultrasound studies for staging of retroperitoneal nodal involvement.

Technical Approach: Patients with histologically confirmed carcinoma of the testis, stage I or stage II, are eligible. Patients should enter the study between two and four weeks after lymphadenectomy. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-14		Status: Closed	
Title: SWOG 8102, Whole Brain Irradiation and Intrathecal Methotrexate in the Treatment of Solid Tumor Leptomeningeal Metastases, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the response-rate (CR + PR) of intrathecal methotrexate and whole brain irradiation in the control of solid tumor leptomeningeal metastases.

Technical Approach: All patients must have cerebrospinal fluid which is cytologically positive for malignant cells. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-15		Status: Closed	
Title: SWOG 8110, Treatment of Advanced Germ Cell Neoplasms of the Testis; A Comparison of Remission Induction With Vinblastine, Bleomycin and Cis-Platinum vs Vinblastine, Cis-Platinum and VP-16-213; Surgical Removal of All Residual Tumor Following Remission Induction; Comparison of Maintenance Therapy With Cyclophosphamide, Actinomycin-D, Adriamycin and Vinblastine vs Observation, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To compare in a randomized fashion the effectiveness of the drug combination Vinblastine, Cis-diamminedichloroplatinum (Cis-platinum) and VP-16-213 versus Vinblastine, Bleomycin and Cis-Platinum in the remission induction of patients with disseminated germ cell neoplasms of testicular origin. 2) To determine the role of six months of maintenance chemotherapy versus observation for those patients who achieve a complete response during induction, or have a totally resected mature teratoma, in terms of relapse-free survival and overall survival. 3) To determine the role of six months of maintenance chemotherapy versus observation for those patients with residual carcinoma having no evidence of disease following surgery, in terms of relapse-free survival and overall survival. 4) To document the nature and extent of the hematologic and non-hematologic side effects of the treatment modalities.

Technical Approach: Patients should have a histologically confirmed diagnosis of disseminated germ cell neoplasms of testicular origin. All patients with bulky abdominal disease (Stage cII (N₄) or Stage cIII) will be eligible for the study. Patients should have an expected survival of at least eight weeks. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-16		Status: Closed	
Title: SWOG 8211, Evaluation of Cis-Diamminedichloroplatinum in Disseminated Gastric Adenocarcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To test the response-rate of cis-diamminedichloroplatinum (DDP) in patients with disseminated and measureable adenocarcinoma of the stomach who are previously untreated. 2) To test the response-rate of cis-diamminedichloroplatinum in patients with disseminated adenocarcinoma of the stomach who are previously treated with 5-fluorouracil, Adriamycin and Mitomycin-C (5-FAM) chemotherapy.

Technical Approach: Eligible patients must have a histologically proven gastric adenocarcinoma and be considered inoperable for cure at the time of entry on the study. Patients must have a life expectancy of six weeks or longer. Therapy will follow the schema outlined in the study protocol.

Progress: One patient was entered on study, then taken off.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 84-17 Status: Closed
 Title: SWOG 8232, Treatment of Limited Small Cell Lung Cancer With VP-16/
 Cis-Platinum, Alternating with Vincristine/Adriamycin/Cyclophosphamide and
 Radiation Therapy Versus Concurrent VP-16/Vincristine/Adriamycin/Cyclophosphamide and Radiation Therapy, Phase III.

Start Date:	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: 1) To compare the efficacy of alternating non-cross-resistant, multidrug regimens with concurrent combination chemotherapy as remission induction in patients with limited small cell lung carcinoma. 2) To determine the toxicity of these treatment programs.

Technical Approach: All patients must have histologically proven small cell carcinoma of the lung. Prior to treatment, patients should be staged as to the extent of disease. Only patients with limited disease are eligible for this study. They must have evaluable or measurable disease. Patients having a prior surgical procedure are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-18		Status: Closed	
Title: SWOG 8237, Evaluation of Continuous Infusion Vinblastine Sulfate in Pancreatic Adenocarcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine the clinical response rate of a five-day continuous infusion of vinblastine sulfate in pancreatic adenocarcinoma.

Technical Approach: To be eligible, patients must have a pathologically verified diagnosis of pancreatic adenocarcinoma. They must have objectively measurable or evaluable lesion(s) excluding CNS metastases and a life expectancy of at least eight weeks. Patients must have recovered from the toxicities of previous chemotherapy and/or radiotherapy and have demonstrated progressive disease. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85	Prot No.: 84-19	Status: Closed
Title: SWOG 8241, Treatment for Advanced Non-Small Cell Lung Cancer: PV _p Versus PV _p M Versus PVe Versus PVeMi Versus FOMi/CAP, Phase III.		

Start Date:	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: 1) To directly compare the efficacy and toxicity of Cis-platinum plus VP-16 (PV_p) versus Cisplatinum plus Vinblastine (PVe) in patients with advanced (TNM Stage III M1) non-small cell lung cancer (NSCLC). 2) To compare the response rate, response duration, survival and toxicity of Cis-platinum plus VP-16 (PV_p) to Cis-platinum plus VP-16 plus MGBG (PV_pM). 3) To compare the response rate, response duration, survival and toxicity of Cis-platinum plus Vinblastine (PVe) to Cis-platinum plus Vinblastine plus Mitomycin-C (PVeMi). 4) To re-evaluate and compare the activity of FOMi/CAP to PV_p, PV_pM, PVe and PVeMi using a five-arm, randomized study design. 5) To evaluate differences in response rates among patients with squamous cell carcinoma, adenocarcinoma or large cell undifferentiated carcinoma of the lung.

Technical Approach: All patients with a histologically or cytologically confirmed diagnosis of squamous cell carcinoma, adenocarcinoma or large cell carcinoma of the lung are eligible for this study. The patient's clinical presentation should be compatible with a neoplasm of bronchogenic origin. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-20		Status: Closed	
Title: SWOG 8294, Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer, Intergroup Study.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) Assess the impact of short-term intensive chemotherapy with CMFP to prevent disease recurrence and prolong survival in N- patients with any size ER- tumors and N- patients with ER+ tumors whose pathological size is greater than or equal to 3 cm. 2) Assess the impact of surgical procedures, ER status, menopausal status and tumor size. 3) Develop guidelines referable to histopathological features of N- tumors which are reproducible and assess their prognostic impact for disease-free survival and survival. 4) Assess the value of CEA in predicting recurrence and survival rates. 5) Assess the natural history of a subgroup with N-, ER+ small tumors (<3 cm).

Technical Approach: All female patients having had at least a total mastectomy with an axillary dissection or total mastectomy with low axillary dissection for potentially curable breast carcinoma as defined in this protocol and having no histopathological evidence of axillary node involvement will be considered for inclusion in this study. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-21		Status: Closed	
Title: SWOG 8302, Phase II Study of Doxorubicin, Mitomycin-C, 5-Fluorouracil in the Treatment of Metastatic Adenocarcinoma of the Prostate.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To test the effectiveness and toxicity of DMF (Doxorubicin, Mitomycin-C and 5-Fluorouracil) in the treatment of Stage D ₂ adenocarcinoma of the prostate.					

Technical Approach: Patients with histologically proven, metastatic adenocarcinoma of the prostate with measurable disease are eligible. Patients with blastic bone lesions on x-ray as a sole manifestation of metastases are not eligible. However, patients with bone metastases only who have positive bone scans will be eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 84-31 Status: Closed
 Title: SWOG 7983, Radiation Therapy in Combination with CCNU in Patients with Incompletely Resected Gliomas of the Brain, Grade I and II.

Start Date:		Est Comp Date:
Principal Investigator(s)		Facility:
Steven A. Madden, MD, MAJ, MC		Eisenhower Army Medical Center
Dept/Svc:		Associate Investigators:
Medicine/Oncology		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To compare the survival of patients with incompletely resected Grade I and II gliomas treated with radiation alone versus radiation and CCNU. 2) To compare the effectiveness of radiation therapy versus radiation therapy plus CCNU for remission induction and duration of remission.

Technical Approach: Patient with histologically confirmed primary brain tumors of the following histologic types are eligible: Astrocytoma, Grade I and II with incomplete tumor resection. Patients who have had surgery with histologic diagnosis within the previous six weeks are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

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CLINICAL INVESTIGATION PROGRAM REPORT RCS MED-300 (R-1) 2/3

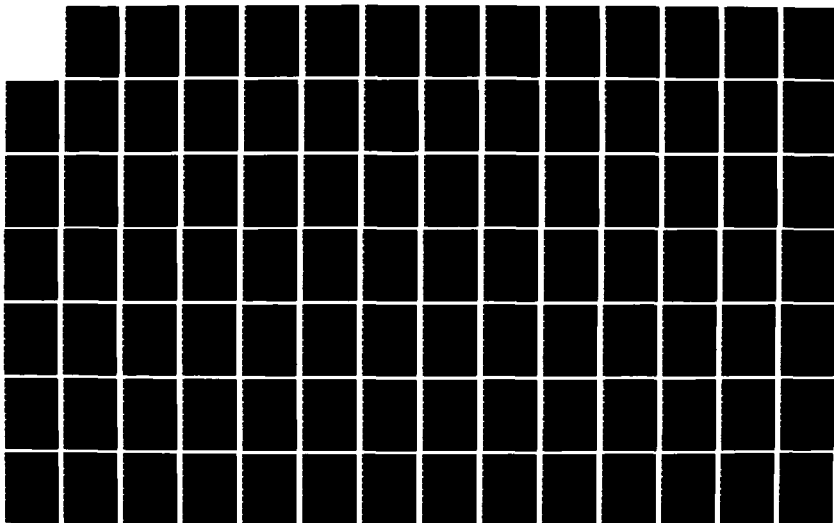
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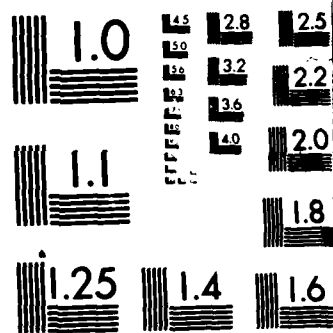
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Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-33		Status: Closed	
Title: SWOG 8024, Combined Modality Therapy for Disseminated Soft Tissue Sarcomas, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, MD, MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To compare the effectiveness of bolus administration of Adriamycin and DTIC, to continuous infusion administration of Adriamycin and DTIC, in remission induction of patients with disseminated soft tissue sarcomas. 2) To compare the toxicities of these two drug schedules. 3) To determine the feasibility on a group-wide basis of surgical excision of accessible lesions in partially responding patients. 4) To compare the histology of the diagnostic lesion with the histology of tumor removed from the partial responder.

Technical Approach: Patients with a biopsy confirmed diagnosis of a soft tissue sarcoma with convincing clinical or biopsy-documented evidence of metastatic disease are eligible for this study. Patients must not have received any prior chemotherapy with the agents used in this study. Patients must have a life expectance of 10 weeks, and all patients must have lesion(s) which is measurable and can be followed for tumor response. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-34		Status: Closed	
Title: SWOG 8026, Cis-Platinum in the Treatment of Refractory Epidermoid Carcinoma of the Penis, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, MD, MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine response-rate and survival in patients with advanced epidermoid carcinoma of the penis treated with Cis-Platinum.

Technical Approach: Patients must have epidermoid carcinoma of the penis confirmed by biopsy, Stage III or IV, refractory to surgery and radiotherapy. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-36		Status: Closed	
Title: SWOG 8049, The Treatment of Resected, Poor Risk Prognosis Malignant Melanoma: Stage I: Surgical Excision vs Surgical Excision + Vitamin A, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, MD, MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine the efficacy of surgical excision or surgical excision plus vitamin A in preventing the recurrence of high risk, Stage I malignant melanoma by determination of remission or disease-free interval. 2) To determine the immunocompetence of patients with malignant melanoma and to determine the influence of vitamin A upon that immunocompetence.

Technical Approach: All patients with a histologically-confirmed diagnosis of high risk Stage I malignant melanoma who have not been previously treated with chemotherapy, radiation therapy, or immunotherapy are eligible. All patients must have had a wide local excision of the primary lesion. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-37		Status: Closed	
Title: SWOG 8092, Use of Human Tumor Cloning System to Select Chemotherapy for patients with Ovarian Cancer Refractory to Primary Therapy, Ancillary Study.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, MD, MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To utilize the human tumor cloning assay to select single agent chemotherapy for patients with epithelial-type ovarian cancer, refractory to standard therapy. 2) To determine if the human tumor cloning system can be utilized to select individual patient's therapy in a cooperative group setting.

Technical Approach: Eligible patients must have a pathological diagnosis of epithelial-type ovarian cancer in pleural or peritoneal fluid. Patients should have measurable disease and a life expectancy of at least 3 months.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-38		Status: Closed	
Title: SWOG 8093, Treatment of Metastatic Malignant Mesothelioma: A Comparison of Cyclophosphamide (Cytosan), DTIC and Adriamycin (CIA) vs Cyclophosphamide and Adriamycin (CA), Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, MD, MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the effect of the drug combination, Cyclophosphamide, DTIC, and Adriamycin vs Cyclophosphamide and Adriamycin (CA) on response-rate, remission duration, and survival of patients with metastatic malignant mesothelioma in a prospective, randomized Phase III clinical trial. To determine the qualitative and quantitative toxicities of these two drug combinations. To conduct an epidemiologic survey on all patients designed to identify important environmental factors which may place an individual at risk for the development of malignant mesothelioma.

Technical Approach: All patients must have histologically proven malignant mesothelioma of pleural or peritoneal origin with evidence of distant metastases or documented failure to previous radiation therapy. There must be an expected survival of at least 8 weeks. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-39		Status: Closed	
Title: SWOG 8094, Radiotherapy with and without Chemotherapy for Malignant Mesothelioma Localized to One Hemithorax, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, MD, MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To evaluate in a randomized prospective manner, the efficacy of Adriamycin in improving the disease-free interval in patients who will receive hemithoracic radiotherapy for Stage I pleural mesothelioma. 2) To further define prospectively the efficacy of radiotherapy to the involved hemithorax in patients with pleural mesothelioma.

Technical Approach: Eligible patients will have histologically confirmed malignant mesothelioma of the pleural cavity. Patients with measurable disease or evaluable disease as well as those in whom all gross disease has been resected will be eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-40		Status: Closed	
Title: SWOG 8104, Treatment of Advanced Seminoma (Stage cII (N ₄) + cIII with Combined Chemotherapy and Radiation Therapy, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, MD, MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the response-rate and survival patterns in patients with advanced seminoma (Stage cII (N₄) + cIII) treated with combined chemotherapy and radiation therapy.

Technical Approach: All patients with histologically proven, Stage cII (N₄) and cIII, advanced, pure or anaplastic testicular seminoma who have had no prior chemotherapy or radiation therapy are eligible. Patients must have no other evidence of malignant disease. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-52		Status: Closed	
Title: SWOG 8107, Management of Disseminated Melanoma, Master Protocol, Phase II-III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the effectiveness of cranial irradiation given electively in disseminated melanoma patients with lung and/or liver metastases to prevent or delay the clinical appearance of brain metastases.

Technical Approach: Patients should have histologic proof of melanoma and a negative radiographic study of the brain. Patients must have established disseminated melanoma with lung and/or liver metastases. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-54		Status: Closed	
Title: SWOG 8122, Combined Modality Treatment of Extensive Small Cell Lung Cancer, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To compare the response rate and duration of a new induction program (multiple alkylating agents plus Vincristine), with emphasis on complete response, to the combination of Vincristine, Adriamycin and Cyclophosphamide in the treatment of extensive small cell lung cancer. To examine the effect of radiation consolidation on relapse in the chest and liver in patients without widespread skeletal disease. To assess qualitative and quantitative toxicity of this combined modality approach. To perform a prospective analysis, by electron microscopy, of the available material for clinicopathologic correlation. To evaluate the effectiveness of a more aggressive radiation therapy approach to clinically evident brain metastases. To evaluate the impact of chest radiation therapy following relapse as to the duration of response and survival. To improve survival and the quality of life in patients with extensive small cell lung cancer.

Technical Approach: All patients with extensive small cell carcinoma of the lung (spread of disease beyond the ipsilateral hemithorax and its regional nodal drainage) are eligible for entry onto this study. Patients must not have had prior treatment with chemotherapy or radiation therapy. Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered on study; taken off 7 Dec 83; expired 31 Dec 83.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-55		Status: Closed	
Title: SWOG 8124/5/6, Treatment of Acute Non-Lymphocytic Leukemia with Conventional Induction, Consolidation Chemotherapy: Maintenance with Chemotherapy vs bone Marrow Transplantation Following Total Body Irradiation, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the complete remission-rate with intensive induction chemotherapy in patients with acute non-lymphocytic leukemia, focusing attention on those patients over 50 years of age.

To compare duration of remission and survival of patients receiving maintenance with or without intensification chemotherapy versus those patients receiving an HLA identical sibling bone marrow transplant while in first remission.

To determine the comparative toxicity of these regimens.

To compare the continuous maintenance therapy and late intensification with late intensification alone.

Evaluate the prognostic significance of any chromosome abnormalities in leukemic cell lines.

Technical Approach: All patients with a diagnosis of acute non-lymphocytic leukemia who have not received prior therapy and who do not have initial CNS leukemia will be eligible for this study. There are no age restrictions; however, patients over the age of 50 will not be considered for bone marrow transplantation.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-56		Status: Closed	
Title: SWOG 8200, Evaluation of Vinblastine by Continuous Infusion for Advanced Recurrent Endometrial Carcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To evaluate the efficacy of a five day Vinblastine infusion with respect to remission induction, remission duration, and survival duration in patients with advanced, recurrent, or Stages III and IV endometrial carcinoma refractory to prior chemotherapy.

Technical Approach: Patients with pathologically proven adenocarcinoma or adenosquamous carcinoma of the endometrium who have recurrent disease, or Stage III or IV disease no longer treatable with radiation therapy or surgery, are eligible. Patients must not have received prior chemotherapy with vinca alkaloids. Patients may have had previous chemotherapy of other types. Patients must have clinically measurable disease either by radiologic techniques or physical examination. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-57		Status: Closed	
Title: SWOG 8208, Trial of Chlorozotocin and 5-FU in Metastatic Islet Cell Carcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To study the response of functioning and non-functioning islet cell carcinoma to chlorozotocin (CTZ) and 5-fluorouracil (5-FU). To determine the toxicity of 5-FU and CTZ when given in combination.

Technical Approach: To be eligible for this study, all patients must have biopsy-proven islet cell carcinoma not amenable to further surgical therapy; and a minimum life expectancy of greater than six weeks. All patients must have objectively measurable disease, or a significant biochemical abnormality secondary to endocrine hyperfunction specific for their islet cell tumors. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 84-60 Status: Closed
 Title: SWOG 8219, Evaluation of Combined or Sequential Chemo-Endocrine
 Therapy in Treatment of Advanced Adenocarcinoma of the Prostate, Phase III.

Start Date:		Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the efficacy of the sequential use of endocrine therapy followed at the time of progression by cytotoxic chemotherapy (Adriamycin and cyclophosphamide) versus the combination of endocrine therapy and chemotherapy together in the treatment of advanced adenocarcinoma of the prostate by determination of the response rate, response duration, and duration of survival.

Technical Approach: All patients with histologically proven, asymptomatic or symptomatic Stage D adenocarcinoma of the prostate are eligible. Patients may not have had previous hormonal therapy or chemotherapy. They should have a life expectancy of six weeks or greater. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-61		Status: Closed	
Title: SWOG 8228, Correlation Between Progesterone Receptor and Response to Tamoxifen in Patients with Newly Diagnosed Metastatic Breast Disease, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To define the prognostic role of progesterone receptor in patients with newly diagnosed metastatic breast disease by correlating progesterone receptor levels with objective response rates in women treated with Tamoxifen.

Technical Approach: Female patients who have new, metastatic breast carcinoma are eligible for this study. Patients who have received prior hormonal adjuvant therapy are eligible, provided that they have not failed during therapy and the therapy has been stopped for at least three months. Patients must be ER+ in order to be eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-62		Status: Closed	
Title: SWOG 8229/30, Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission Induction Therapy: VMCP + Levamisole vs Sequential Half-Body Radiotherapy + Vincristine-Prednisone for Maintenance or Consolidation. Evaluation of Half-Body Radiotherapy + Vincristine-Prednisone for Patients Who Fail to Achieve Remission Status with Chemotherapy Alone, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To compare the effectiveness of two intermittent pulse schedules of the chemotherapy combination of Vincristine, Melphalan, Cyclophosphamide and Prednisone (VMCP) plus Vincristine, BCNU, Adriamycin and Prednisone (VBAP) (alternating versus syncopated) for the induction of remissions in previously untreated patients with multiple myeloma.

For patients proven to achieve remission (at least 75% tumor regression after induction), to compare the value of 12 months of chemoimmunotherapy maintenance, VMCP + Levamisole, versus a consolidation program consisting of sequential half-body radiotherapy along with Vincristine and Prednisone followed by unmaintained remission.

For patients who only achieve improvement (50%-74% tumor regression) on chemotherapy induction, to determine whether sequential half-body radiotherapy along with Vincristine and Prednisone will increase the remission rate (at least 75% tumor regression).

To determine whether sequential half-body radiotherapy along with Vincristine and Prednisone can serve as an effective form of induction therapy for patients who fail to respond to chemotherapy or suffer early relapse.

Technical Approach: Only previously untreated patients with the diagnosis of multiple myeloma are eligible. This is a first-line study and only patients without prior cytotoxic chemotherapy are eligible.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-63		Status: Closed	
Title: SWOG 8231, Chemotherapy of Extragenadal Germinal Cell Neoplasms, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the effectiveness of alternating combination chemotherapy consisting of VBP (Vinblastine, Bleomycin and Cis-Platinum) and EBAP (Bleomycin, Adriamycin, Cis-Platinum and VP-16) in patients with metastatic germinal cell neoplasms arising in extragonadal sites.

To determine the overall toxicity of the alternating combination of VBP and EBAP.

To determine the role of surgical removal of residual disease following this drug combination in partially responding patients.

To compare the response rates observed in this study with those reported by other investigators.

Technical Approach: Patients presenting with a histologically confirmed diagnosis of non-resectable extragonadal germ cell tumors are eligible for this study. All patients should have clearly measurable disease, or an abnormally elevated beta HCG and/or alpha fetoprotein. Patients with extragonadal seminomatous and non-seminomatous neoplasms will be eligible for treatment on this study, but will be analyzed separately. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-64		Status: Closed	
Title: SWOG 8235, Evaluation of Continuous Vinblastine in Gastric Carcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the response rate, response duration, and duration of survival of gastric carcinoma treated with continuous infusion vinblastine.

To define the qualitative and quantitative toxicities of continuous infusion vinblastine administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of adenocarcinoma of the stomach with gross unresectable residual disease. Both previously treated and untreated patients will be eligible for this study. Patients must have measurable disease. patients must not be receiving concomitant radiation therapy, hormonal therapy, or other chemotherapy while on this protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-65		Status: Closed	
Title: SWOG 8244, Clinical Antitumor Activity of Vinblastine Sulfate in Diffuse Mesothelioma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the clinical response rate of five-day continuous infusion vinblastine sulfate in diffuse malignant mesothelioma.

Technical Approach: To be eligible, patients must have a pathologically verified diagnosis of mesothelioma. The mesothelioma may arise either in the thorax or abdomen, but must be of the diffuse malignant type (i.e., not locally resectable by surgery). Patients must have objectively measurable or evaluable lesion(s) excluding CNS metastases and a life expectancy of at least eight weeks. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-68		Status: Closed	
Title: SWOG 8291, The Intergroup Adult Adjuvant Soft Tissue Sarcoma Study #1. A Randomized Trial of Adjuvant Doxorubicin (Adriamycin NSC#123127) versus Standard Therapy (A Delay of Chemotherapy Until the Time of Possible Relapse)					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: This prospective randomized study is designed to evaluate the efficacy of adjuvant Adriamycin compared to standard treatment (a delay of chemotherapy until the time of demonstrated relapse) in the management of patients with Stages IIB, IIIA-C and tissue sarcoma in terms of local recurrence rate, disease-free interval, and survival.

Technical Approach: For inclusion in this study, patients must have a histopathologically proven diagnosis of soft tissue sarcoma Stages IIB, IIIA-C, and IVA. The tumor may be either previously untreated or a local recurrence.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85	Prot No.: 84-69	Status: Closed
Title: SWOG 8292, Treatment for Brain Metastases, Phase III. Intergroup Study (Surgery and/or Radiation Therapy).		
Start Date:	Est Comp Date:	
Principal Investigator(s)	Facility:	
Steven A. Madden, M.D., MAJ, MC	Eisenhower Army Medical Center	
Dept/Svc:	Associate Investigators:	
Medicine/Hematology-Oncology		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To test whether the addition of surgery before radiation therapy is a significant improvement over radiation therapy alone in the treatment of patients with apparent single brain metastases. Endpoints studied will be:

One year survival rates and median survival times.

Local control rates of brain metastases one month and six months after treatment.

Improvement of neurological deficit as measured by the percentage of patients with improved neurological function.

To evaluate patient refusal with respect to the surgical component.

Technical Approach: All patients having histologically confirmed cancer with evidence of a potentially resectable single intracranial mass lesion as documented by a contrast-enhanced CAT scan are eligible. Only patients with apparently resectable cerebellar or cerebral cortex lesions will be eligible. Patients with bronchogenic carcinoma should have control of the primary tumor and no other metastases prior to admission on this study.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-71		Status: Closed	
Title: SWOG 8311, Combination Chemotherapy with Cis-Platinum, Vinblastine, and Methylglyoxal Bis (Guanylhydrazine) (MGBG) in Epidermoid Carcinoma of the Esophagus, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To define the response rate and duration, as well as survival duration, in patients with advanced epidermoid carcinoma of the esophagus when treated with Cis-platinum, Vinblastine and MGBG.

To determine the toxicity of this regimen in the treatment of epidermoid carcinoma of the esophagus.

Technical Approach: All patients must have measurable disease and must have histologically or cytologically confirmed diagnosis of epidermoid carcinoma of the esophagus. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85 Prot No.: 84-75 Status: Closed
 Title: SWOG 8364, Immediate Post-Operative Adjuvant Chemotherapy in Patients with Operable Breast Cancer, Phase II-Pilot.

Start Date:	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To assess the toxicity of immediate chemotherapy with Cyclophosphamide, Methotrexate, 5-Fluorouracil, Vincristine and Prednisone beginning at the time of surgery in patients with Stage II carcinoma of the breast.

Technical Approach: All female patients with biopsy proven disease of breast cancer (may be frozen section) which appears to be operable. Patients with clinical T₁₋₃N₀₋₁ are eligible. Chemotherapy must be started within 24 hours of modified radical mastectomy of lumpectomy with axillary dissection. Patients having needle biopsy, incisional or excisional biopsy prior to more definitive surgery ("two-step procedure") must have the definitive surgery within 48 hours of biopsy and chemotherapy within 24 hours of surgery to minimize any lag time between manipulation of tumor and administration of cytotoxic agents. Receptor studies should be performed at the time of biopsy or definitive surgery. Patients who are found to have metastatic disease or T₁N₀ disease after pathologic staging (permanent sections) will be removed from the study and will receive no more than the first course of chemotherapy. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85		Prot No.: 84-76		Status: Closed	
Title: SWOG 8393, National Intergroup Protocol for Intermediate Thickness Melanoma 1.0 to 4.0 MM - Evaluation of Optimal Surgical Margins (2vs4 cm) Around the Primary Melanoma and Evaluation of Elective Regional Lymph Node Dissection.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: Determine whether it is necessary to perform a wide local excision for local control of primary melanomas measuring 1 to 4 mm in thickness. Determine whether the timing of surgical lymphadenectomy for regional node metastatic disease influences survival rates in those patients selected by prognostic factors analysis who are at risk for micrometastases confined to their lymph nodes.

Technical Approach: Eligible patients with melanomas on the trunk or proximal extremity will be prospectively randomized into 2 groups: 1) standard wide excision of at least 4 cm of healthy tissue from the margin of the primary or the scar resulting from excisional biopsy of the primary lesion, 2) an excision with margins 2 cm from the edge of the primary lesion or the biopsy scar. Eligible patients with melanomas on the head, neck and distal extremity will all have a definitive excision with a 2 cm margin of skin.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85		Prot No.: 84-77		Status: Closed	
Title: SWOG 8293, Intergroup Phase III Protocol for the Management of Locally or Regionally Recurrent but Surgically Resectable Breast Cancer.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine whether the application of aggressive chemotherapy and radiation therapy as single modalities or in sequential combination in patients with technically resectable locally or regionally recurrent carcinoma of the breast will result in increased survival and/or prolonged disease-free interval.

Technical Approach: Patients allocated to Schema C will be randomized at the time of registration to one of the 3 treatment plans: Chemotherapy followed by radiation therapy (Treatment Arm I), chemotherapy followed by observation (Treatment Arm II), or radiation therapy followed by observation (Treatment Arm III).

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85		Prot No.: 84-78		Status: Closed	
Title: SWOG 8300, Treatment of Limited Non-Small Cell Lung Cancer: Radiation vs Radiation Plus Chemotherapy (FOMi/CAP), Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To compare combination chemotherapy (FOMi/CAP) plus radiotherapy to radiotherapy alone for patients with limited, non-small cell lung cancer (NSCLC) in a randomized study with stratification for known important prognostic factors with regard to response rate, reponse duration and survival duration. 2) To determine the toxicity of radiotherapy plus FOMi/CAP relative to radiotherapy alone for patients with limited NSCLC. 3) To evaluate the responsiveness of smaller tumor burdens to FOMi/CAP (i.e., less than metastatic disease). 4) To determine the pattern of relapsing disease in each treatment arm and in subgroups of patients determined by histology and response to FOMi/CAP. 5) To determine if prophylactic brain irradiation will decrease the chances for brain metastases and influence toxicity or survival.

Technical Approach: All patients must have a histologic or cytologic diagnosis of non-small cell carcinoma of the lung (squamous, large cell undifferentiated or adenocarcinoma). Cytology should be confirmed at least twice. Patients must have limited disease. Disease must be confined to a single hemithorax, and/or the ipsilateral hilar lymph nodes, and/or the mediastinum, and/or the ipsilateral supraclavicular lymph nodes. In addition, the patient's disease must be encompassable in a single radiation port. Patients with pleural effusion are not eligible for the study if the effusion is considered to be malignant. A radiation oncology consult is required prior to patient registration. Patients must have unresectable disease (Stage II or IV).

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85		Prot No.: 84-79		Status: Closed	
Title: SWOG 8308, Combination of Cis-Platinum and Dichloromethotrexate in Patients with Advanced Bladder Cancer, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To obtain data regarding the activity and toxicity of combination cis-platinum and dichloromethotrexate in patients with objectively measurable metastatic transitional cell carcinoma of the bladder who have good renal function and who have not previously received chemotherapy. 2) To investigate the single agent activity and toxicity of dichloromethotrexate in previously untreated patients with impaired renal function.

Technical Approach: All patients must have a histologically confirmed diagnosis of metastatic transitional cell carcinoma of the urothelium. Only patients without prior systemic chemotherapy (prior intravesical therapy allowable) are eligible for this study. Patients with prior radiotherapy are eligible if the disease has progressed, if at least six weeks have elapsed since completion of the radiotherapy (non-cranial) and if measurable sites of disease exist outside of the previous radiation field. Patients must have a performance status of 3 or better (Karnofsky Scale, >50). All patients must have at least one bidimensional (perpendicular diameters) objectively measurable site of disease.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85		Prot No.: 84-80		Status: Closed	
Title: SWOG 8312, Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in combination as Second-Line Endocrine Therapy of Estrogen Receptor Positive Metastatic Breast Cancer, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine whether combination hormonal therapy with Aminoglutethimide and Hydrocortisone (AH) plus Megestrol Acetate (M), agents thought to have different mechanisms of action, offers an improved response rate with prolonged response duration and increased patient survival over the sequential use of each agent in Estrogen Receptor (ER) positive patients who have progressed after responding to primary hormonal treatment with Tamoxifen. 2) To assess the relative toxicities of Megestrol acetate and medical adrenalectomy. 3) To assess the value of progesterone receptor (PgR) in predicting subsequent responses to a variety of hormonal therapies.

Technical Approach: Post-menopausal female patients with progressive, measurable metastatic breast carcinoma are eligible for this study. The post-menopausal state is defined as 1) physiologic menopause at least one year prior to entry or 2) previous surgical castration for reasons unrelated to breast cancer. Patients with previous hysterectomy should have post-menopausal levels of FSH and LH.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85		Prot No.: 84-81		Status: Closed	
Title: SWOG 8313, Multiple Drug Adjuvant Chemotherapy for Patients with ER Negative Stage II Carcinoma of Breast, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To compare through a randomized prospective study, the recurrence rates and disease-free intervals (DFI) for post-operative axillary node positive estrogen receptor negative (ER-) breast cancer patients given adjuvant therapy with either short term intense chemotherapy (FAC-M) or one year standard chemotherapy (CMFVP). 2) To compare the effect of these two adjuvant therapies on survival. 3) To compare the relative toxicity of the two therapies.

Technical Approach: All patients must have histologically proven breast carcinoma with metastases to one or more axillary nodes (Stage II or III T₁₋₃aN₁) to be eligible. The tumor must be classified according to TNM Classification. The primary tumor must be movable in relation to the anterior chest wall and must not be involved with skin ulcerations. Axillary nodes must be movable in relation to the chest walls and vessels, and there can be no edema of the arm pre-operatively.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85		Prot No.: 84-82		Status: Closed	
Title: SWOG 8325, Combination Chemotherapy with O,P'-DDD and Cis-Platinum in Metastatic Adrenal Carcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To study the responsiveness of adrenocortical carcinoma to combination chemotherapy consisting of Cis-Platinum (DDP) and Mitotane (O,P'-DDD). 2) To study the prognostic features of patients with metastatic and/or unresectable adrenal carcinoma receiving chemotherapy. 3) To document the toxicity of chemotherapy in this group of patients.

Technical Approach: Patients with metastatic or residual adrenocortical carcinoma in whom further surgical removal of disease is not possible will be eligible. All patients should have an expected life span of >4 weeks. Objectively measurable disease on physical examination or x-ray studies, or the presence of a biochemical abnormality specific for that patient's tumor, e.g., elevated urinary 17-keto- or 17 hydroxycorticoids, must be present.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85		Prot No.: 84-83		Status: Closed	
Title: SWOG 8386, Evaluation of Fludarabine Phosphate in Colorectal Carcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine the antitumor activity of Fludarabine Phosphate in patients with colorectal carcinoma by determination of the response-rate and remission duration. 2) To further define the qualitative and quantitative toxicities of this drug in a Phase II study.

Technical Approach: Patients must have biopsy proven adenocarcinoma arising from the colon or rectum. Patients must have clinically measurable recurrent or disseminated disease to qualify for the study. Clearly defined lesions on liver scans or roentgenograms are acceptable. Patients must have a life expectancy of at least ten weeks and a performance status of 0-2 by Southwest Oncology Group criteria.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85		Prot No.: 84-84		Status: Closed	
Title: Combination Chemotherapy of Intermediate and High Grade Non-Hodgkin's Lymphoma with m-BASOD, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine an approximate complete remission rate and remission duration for the treatment program of cyclophosphamide, doxorubicin, vincristine, dexamethasone, and bleomycin with intervening moderate dose methotrexate and leukovorin rescue (m-BACOD), in patients with intermediate and high grade non-Hodgkin's lymphoma. 2) To assess the feasibility of using this regimen in the Southwest Oncology Group with the intent of using m-BACOD in a future Phase III trial.

Technical Approach: Patients must have biopsy proven Stage II-IV non-Hodgkin's lymphoma, intermediate or high-grade histology. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85 Prot No.: 84-85 Status: Closed
 Title: SWOG 8411, Evaluation of DTIC in Metastatic Carcinoid, Phase II.

Start Date:		Est Comp Date:
Principal Investigator(s)		Facility:
Steven A. Madden, M.D., MAJ, MC		Eisenhower Army Medical Center
Dept/Svc:		Associate Investigators:
Medicine/Hematology-Oncology		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To determine the effectiveness of dimethyl triazeno imidazole carboxamide (DTIC) in the treatment of metastatic carcinoid. 2) To determine the survival of patients with metastatic carcinoid receiving DTIC.

Technical Approach: Patients must have biopsy proven carcinoid tumor not amenable to further surgical therapy. Patients must have a minimum life expectancy of 6 weeks. All patients must have objectively measurable disease either as a measurable lesion, or significant biochemical abnormality specific for their tumor (elevated urinary 5-HIAA documented on 2 separate occasions).

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85	Prot No.: 84-86	Status: Closed
Title: SWOG 8415, Evaluation of Tamoxifen in Unresectable and Refractory Meningiomas, Phase II.		
Start Date:	Est Comp Date:	
Principal Investigator(s)	Facility:	
Steven A. Madden, M.D., MAJ, MC	Eisenhower Army Medical Center	
Dept/Svc:	Associate Investigators:	
Medicine/Hematology-Oncology		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the antitumor activity of Tamoxifen in meningiomas not amenable to surgery or radiotherapy. To estimate the response rate and response duration experienced by these patients.

Technical Approach: All patients must have a biopsy proven diagnosis of benign meningioma. All patients must have measurable disease by CT scan or NMR scan. Patients must be unresectable for medical or technical reasons, or have measurable residual disease.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 85 Prot No.: 84-87 Status: Closed
 Title: SWOG 8490, Phse II Study of PAC (Cis-Platinum, Adriamycin, and Cyclophosphamide) in Treatment of Invasive Thymoma, Intergroup Study.

Start Date:		Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the objective response rate in extensive and limited invasive thymoma treated with PAC (Cis-Platinum, Adriamycin, Cyclophosphamide). To determine the duration of remission of patients with limited invasive thymoma treated with split course radiotherapy plus PAC and in patients with extensive disease treated with PAC alone.

Technical Approach: All patients must meet the following criteria: Locally invasive, recurrent or metastatic thymoma; histologic confirmation by Group pathologist; at least one bidimensional measureable lesion; serum creatinine of 1.5 mg/dl or less, or creatinine clearance of 70 ml/minute or better; serum bilirubin of 2.0 mg/dl or less; no prior chemotherapy with alkylating agents, Adriamycin or Cis-Platinum; no prior history of congestive heart failure; performance status 40% or better (Karnofsky); WBC $\geq 4,000/\mu\text{l}$, platelet count $\geq 125,000/\mu\text{l}$.

Progress: No patients were enrolled at DDEAMC.

Detail Summary Sheet

Date: 23 Sep 85 Prot No.: 83-26 Status: Terminated
 Title: Sixteen Personality Factor Profile Responses and Demographic Data
 Used as Predictors of Final Student Rankings in a Practical Nurse
 Course.

Start Date: Jul 83		Est Comp Date:
Principal Investigator(s) Joseph M. Mucha, Jr., MAJ, ANC		Facility: Eisenhower Army Medical Center
Dept/Svc: Nursing		Associate Investigators:
Key Words: Predictors of Final Student Rankings		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To utilize a demographic and personality questionnaire to identify those students who will be successful in completing the Practical Nurse Course.

Technical Approach: Practical Nurse Course students did a completion of the Sixteen Personality Factor Profile and investigator-prepared Demographic Data questionnaires.

Subjects enrolled to date: 70

Progress: Investigator PCS'd, did no submit final report.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-3		Status: Completed	
Title: The Effects of Heated and Humidified Anesthetic Gases on Core Body Temperature.					
Start Date: Nov 83			Est Comp Date: Nov 84		
Principal Investigator(s) Christopher A. Krupp, CPT, ANC Eugene J. Murdock, Jr., CPT, ANC Cheryl S. Beaubé, CPT, ANC Robert Marchi, CPT, ANC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Nursing/Anesthesiology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the change in core body temperature in those patients receiving heated/humidified gases versus those patients receiving the common method of gas delivery-ambient temperature/dry.

Technical Approach:

- 1) Experimental design: a post-test only, equivalent - group experimental design will be used in this study. Random selection of the research population will be carried out using a table of random numbers with subjects being divided into an experimental and a control group. Following data collection, a statistical analysis using the student test will be performed. The results of our analysis will compare the independent variables (heated and humidified anesthetic gases) and the dependent variables (core body temperature) of the two groups.
- 2) Manpower: Investigators listed above.
- 3) Experimental subjects: 19
Control subjects: 19
- 4) Significant adverse reactions: None.
- 5) Funding: None.
- 6) The design was a post-test only, equivalent-group experimental design.

Progress: Population: Thirty-eight, ASA I, randomly assigned, between the ages of 18 and 51 scheduled for elective surgery not involving major body cavities (i.e., thoracic, abdominal, cranial).

Methods of data collection: Experimental esophageal and operating room temperatures, as well as, heater humidifier settings were recorded immediately post-intubation and every 15 minutes thereafter for the remainder of the surgical procedure.

84-3 Continued

Methods of data analysis: Data from the two groups were compared using paired data statistical analysis and differences between the two means were tested for statistical significance (LOS .01) by using the Student t-test. Standard deviation and standard errors of the mean were calculated as described by Freund.

Finding: There was a clinically and statistically significant ($p < .005$) difference in the control and experimental groups.

Conclusions and recommendations: From these observations the investigators concluded that heating and humidifying the anesthetic gases during a general anesthetic aided in the maintenance of patients' core body temperatures.

Detail Summary Sheet

Date: 1 Oct 85	Prot No.: 84-73	Status: Ongoing
Title: Transition into Military Nursing: An Evaluation of A Preceptorship Program.		
Start Date: Sep 84	Est Comp Date:	
Principal Investigator(s) Bruce C. Allanach, LTC, AN	Facility: Eisenhower Army Medical Center	
Dept/Svc: Nursing	Associate Investigators: Bonnie Jennings, MAJ, AN	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jul 85 Review Results Continue

Study Objective: Examine those factors which facilitate the integration of new ANC officers into a hospital nursing milieu. Determine whether locus of control, as well as affective states of anxiety, hostility, and depression are prime factors in the integration of new ANC officers. Develop a protocol which examines whether there are any differences among nurse preceptees within the same preceptorship program who are judged to be a success. The literature reflects that participants in such programs evaluate the programs as successful. Locus of control and multiple affective states may underscore differences in participants evaluation of a program as successful. A preceptorship program is geared to ease transition phenomenal among new nurses who are prone to affective states associated with change such as anxiety, hostility, and depression.

Technical Approach: The data collection for each preceptee occurs over a period of 26 weeks. The plan is evaluation research using a time-series design. The effects of the program will be examined against the goals through a series of measurements during week 1, 4, 8, 9, 13, and 24 after arrival at DDEAMC. These points of time include before the program begins, during the program, and after the program ends. The principal investigator administers the tools.

Subjects enrolled to date: 26
Subjects enrolled for reporting period: 14

Progress: Since inception of the investigation, 26 AN officers have completed the preceptorship program and all phases of data collection. Two others have completed testing through the ninth week. They will complete testing by the end of December 1985. Eight more AN's were enrolled in September 1985. This will achieve the "N" projected in the design.

Detail Summary Sheet

Date: 31 Oct 85	Prot No.: 84-74	Status: Terminated
Title: Religiosity, Anxiety, and Patient Satisfaction in a Group of Seriously Ill Cancer Patients.		
Start Date: Oct 84	Est Comp Date: Jan 85	
Principal Investigator(s) Rosa Maria Baunchalk, CPT, ANC	Facility: Eisenhower Army Medical Center	
Dept/Svc: Medicine/Oncology/Nursing	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 85 Review Results

Study Objective: An attempt to demonstrate the significance of religiosity in a group of seriously ill cancer patients. The relationships between religiosity, anxiety, and patient satisfaction with nursing care will be examined.

Technical Approach: A convenience sample of 20-30 oncology inpatients will be selected for this study. The demographic and research data obtained will be entered into a computer with the subject's identifying code number only. Three instruments will be used: The Religious Belief Questionnaire, the state anxiety scale from the State-Trait Anxiety Inventory, and the Patient Satisfaction Instrument.

Progress: Investigator ETS'd, unable to obtain a final report.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 85-3		Status: Completed	
Title: Effectiveness of Droperidol in Reducing the Incidence of Nausea and Vomiting After the Use of Etomidate for Induction in Surgical Patients Undergoing General Endotracheal Inhalation Anesthesia.					
Start Date: Jan 85			Est Comp Date: Aug 1985		
Principal Investigator(s) Nancy M. Simpson, MAJ, AN Virginia G. Holliday, CPT, AN Lois J. Manning, CPT, AN Thomas W. Overly, CPT, AN			Facility: Eisenhower Army Medical Center		
Dept/Svc: Nursing/Anesthesiology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine what effect, if any, droperidol has in reducing the incidence of nausea and vomiting associated with the use of etomidate.

Technical Approach: Twenty-four surgical patients received etomidate for induction of anesthesia. Two groups were formed using a table of random numbers, one group was pretreated with droperidol and the other group was not pretreated with droperidol. The patients were then evaluated in the recovery room for the incidence of nausea, retching and vomiting.

The design was an experimental design.

Progress: Population: Twenty-four ASA I, randomly assigned, between the ages of 18 and 59, scheduled for elective surgery no involving the intestinal tract, upper abdominal, GYN procedures, and EENT procedures.

Methods of data collection: The data collection period began at the time of extubation and continued for two hours. The incidence of nausea, retching and vomiting were recorded every 15 minutes by the recovery room nurses.

Methods of data analysis: Data from the two groups were compared using a Chi-square test of independence at the 0.05 level of significance with one degree of freedom.

Finding: There was not a statistically significant difference in the control and experimental groups.

Conclusions and recommendations: From these observations the investigators concluded that there was no statistically significant difference in the incidence of nausea, retching and vomiting when surgical patients were pretreated with droperidol and etomidate was used as the induction agent for anesthesia.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 85-33		Status: Completed	
Title: Contributions of an Educational Program to the Psychosocial Well Being of Patients Who Have Undergone Vertical Banded Gastroplasty for Morbid Obesity.					
Start Date: Jun 85			Est Comp Date: Sep 85		
Principal Investigator(s) Elaine Allanach, CPT, AN			Facility: Eisenhower Army Medical Center		
Dept/Svc: Nursing			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To identify positive psychosocial changes from an educational program designed for patients who have had a vertical banded gastroplasty.

Technical Approach: Psychosocial well being to be identified using tools from the Clinical Measurement Package. Seven of the tools were administered on 1 June 1985, after which those patients attended six classes and were to be retested on 9 September 1985, using the same tools. Comparisons between pre and post tests were to be made, and descriptive analysis completed.

Manpower: No extra manpower used outside of investigators.

Number of subjects enrolled: 10.

Progress: Ten tools were completed on 1 June 1985 by the patient volunteers. A six week educational program was conducted and completed during the summer involving these 10, and others who wished to attend. Difficulties with the group process have occurred which has interfered with the patients completing the post tests. Only two have been returned to date (the patients refused to complete them on 9 September as originally planned). We doubt that we will be able to retrieve the data we were desiring. The following is a summary of the factors that have interfered with the plan:

- 1) Unplanned PCS move of one investigator, Major Hugh Turcotte, in late August.
- 2) Unplanned exit of primary investigator, Captain Allanach, from her role, due to nursing staff shortage, in late August.
- 3) Postoperative death of a gastroplasty patient, in early September, which heightened fears and anxieties of group members about their own postop health. A sub issue here dealt with the patients sense of trust in regards to the safety of the procedure.
4. Decision of groups' president, who is the prime mover for the Gastroplasty Support Group, to not seek re-election in the fall. Disbanding of the group became a major subtopic in their frustration.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 84-49 Status: Terminated
 Title: The Role of Stress in the Etiology of Obesity.

Start Date: Jun 84		Est Comp Date:
Principal Investigator(s) Janet G. Tingle, CPT, AMSC		Facility: Eisenhower Army Medical Center
Dept/Svc: Nutrition Care Division		Associate Investigators: Katie Boyd, LTC, AMSC
Key Words: Stress/Trauma/Obesity		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To investigate the possible role of stress or trauma in the development of obesity.

Technical Approach: a. Two separate studies are being conducted. In study one, post multiple fracture patients are contacted through the mail and asked to complete a questionnaire dealing with stress, eating habits, and weight control. In the second study, known obese and "ideal" weight males and females between the ages of 30 and 50 are interviewed through a questionnaire and a personal interview about stress, eating responses, development of a weight problem, etc. Skinfold measurements are done on each of these subjects.

Progress: Investigator PCS'd, did not submit final report.

Detail Summary Sheet

Date: 23 Oct 85		Prot No.: 85-12		Status: Ongoing	
Title: Comparison of Single Dose Cefoxitin Prophylaxis for Cesarean Section.					
Start Date: Jan 85			Est Comp Date: Oct 86		
Principal Investigator(s) James F. Flaherty, MAJ, MC			Facility: DDEAMC, Talmadge Memorial and University Hospitals		
Dept/Svc: Obstetrics-Gynecology			Associate Investigators: Charles Brown, M.D. Hamid A. Hadi, M.D.		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: This randomized prospective investigation will evaluate the efficacy of a single two gram dose of cefoxitin at time of cesarean section by IV bolus injection after cord clamping or by lavage administration.

Technical Approach: Three treatment groups are defined: a control group will receive no antibiotics; one antibiotic group will receive a bolus injection of two grams of cefoxitin after the umbilical cord is clamped; the second antibiotic group treatment group will receive uterine and peritoneal lavage of two grams cefoxitin in one liter of normal saline after the placenta is delivered.

Subject population. Any gravid adult female patient with labor and/or rupture of membranes longer than three hours will be candidates for the investigation.

Number of subjects enrolled for the reporting period: 60

Progress: Data is being collated. Anticipate another 12 months until completion.

Detail Summary Sheet

Date: 29 Oct 85		Prot No.: 85-27		Status: Ongoing	
Title: Training Laboratory for Obstetrics and Gynecologic Residents Utilizing Rabbits.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Adolphus Foreman, M.D., LTC, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
OB/GYN, Clinical Investigation			James Flaherty, M.D., MAJ, MC		
Key Words:			William Aultman, M.D.		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To familiarize residents in the Department of Obstetrics and Gynecology with microsurgery techniques in tubal reanastomosis.					

Technical Approach: Rabbits will be anesthetized and a laporatomy will be performed. The fallopian tubes will be incised and reanastomosed. Animals will be euthanized one week post surgery and histology of fallopian tubes performed.

Manpower - use of veterinary assistant for 2-hour period on one occasion.

Progress: During a pilot study, one rabbit was laparotomized, fallopian tubes incised and reanastomosed. The animal recovered uneventfully. We plan to continue the study on a recurring basis.

Detail Summary Sheet

Date: 23 Oct 85		Prot No.: 85-28		Status: Ongoing	
Title: A Multicenter Study Comparing Intravenously Administered Apallicillin and Piperacillin in the Treatment of Hospitalized Patients with Infections Caused by Susceptible Aerobic and Anaerobic Bacteria.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Gerald Holzman, M.D.			Eisenhower Army Medical Center		
James Flaherty, M.D., MAJ, MC			Associate Investigators:		
Dept/Svc:					
Obstetrics-Gynecology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective:					

Technical Approach:

Progress: Attempts to coordinate sensitivity testing still being pursued. Study being held at HSC for drug use approval until sensitivity testing problem is resolved.

Detail Summary Sheet

Date: 23 Oct 85		Prot No.: 85-29		Status: Ongoing	
Title: A Multicenter Double-Blind Comparison of Intravenously Administered Apalacillin and Cefoxitin for the Prevention of Postoperative Infection in Patients Undergoing Vaginal or Abdominal Hysterectomy.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Gerald Holzman, M.D.			Eisenhower Army Medical Center		
James Flaherty, M.D., MAJ, MC			Associate Investigators:		
Dept/Svc:					
Obstetrics/Gynecology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective:					

Technical Approach:

Progress: Attempts to coordinate C/S testing at MCG sill ongoing. Study being held at HSC for drug use approval until C/S testing problem is solved.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-4		Status: Ongoing	
Title: Metastatic Adenocarcinoma of Unknown Primary Site.					
Start Date: Nov 83			Est Comp Date: May 85		
Principal Investigator(s) Ricky Reaves, M.D., CPT, MC Phyllis Brewer Jack A. Horner			Facility: Eisenhower Army Medical Center		
Dept/Svc: Pathology Clinical Investigation			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine whether or not the primary site of a metastatic adenocarcinoma of unknown origin can be determined with a high degree of accuracy.

Technical Approach: (1) Gathering cases where primary tumor site is unequivocal.

(2) Manpower: Three.

(3) Morphometric measurements will be made on tumors from known primary sites (adenocarcinomas only) to determine if a statistically significant difference in microvillus size can be assigned to the various primary organs.

Progress: Morphometric measurements have been completed on 12 cases representing four different known primary sites. Only in the case of lung as a primary site has there been a sample size large enough to begin to look for a statistical correlation (n=7). The preliminary assessment is encouraging, but many additional samples are required. The study is continuing as suitable samples become available.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 85-9		Status: Completed	
Title: Use of Mice in Rabies Diagnosis.					
Start Date: Jan 85			Est Comp Date: Jul 85		
Principal Investigator(s) Byron L. Wilson, LTC, VC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Pathology/Veterinary Laboratory			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: This protocol establishes a standing procedure for the use of mice in performing the mouse inoculation test which is used to isolate rabies virus, and in performing the fluorescent rabies antibody test which is used to demonstrate rabies virus antigen in specimens.

Technical Approach:

a. Summary of experimental design. A suspension of an animal brain which is suspected of containing rabies virus is injected intracerebrally into five 3-week-old mice. The mice are observed for 30 days. Those which show signs of rabies are tested with fluorescent rabies antibody.

b. Manpower. A veterinary laboratory officer and a medical technician.

c. Funding. Veterinary Lab supply budget funds (est \$850) were used.

Progress: This study was terminated 9 July 1985 when rabies testing by the Veterinary Laboratory was stopped due to the impending lab closure 1 September 1985. From January 1985 to 9 July 1985, mice were successfully used to diagnose 74 cases of suspected animal rabies.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 85-4 Status: Ongoing
 Title: Training Laboratory for Neonatal Procedures.

Start Date:		Est Comp Date:
Principal Investigator(s) W. Michael Southgate, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Pediatrics, Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To familiarize residents on rotation through the Department of Pediatrics with endotracheal intubation procedures in the newborn.

Technical Approach: Practice placement of endotracheal tubes. Involves two technicians in Clinical Investigation, staff pediatrician and three to five students.

Progress: Each four week period, four residents are instructed in the method of tracheal intubation used in neonates. In addition to this, the students see a comprehensive film on newborn resuscitation and practice placing umbilical artery catheters into severed, preserved umbilical cords.

Detail Summary Sheet

Date: 21 Oct 85		Prot No.: 84-1		Status: Ongoing	
Title: The DDEAMC Alcohol Residential Treatment Facility Patient Outcome Study.					
Start Date: Oct 83			Est Comp Date:		
Principal Investigator(s)			Facility:		
Michael Deeken, M.D., MAJ, MC			Eisenhower Army Medical Center		
John J. Haskin, M.D., MAJ, MC					
Peter S. Jensen, M.D., MAJ, MC					
Daniel Hendricks, CPT, MSC					
Dept/Svc:			Associate Investigators:		
Psychiatry and Neurology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic May 85 Review Results	

Study Objective: To better understand alcoholism and its treatment by assessing some of its biological, psychological, and social concomitants, and determining their diagnostic and prognostic validity.

Technical Approach:

1. Summary of Experimental Design: This study is prospective in design. Measures of the above mentioned variables will be taken prior to, and upon completion of, treatment. Additionally, follow-up questionnaires are to be completed by the patient, spouse, and patient's commander at intervals of three, six, nine, twelve, and twenty-four months after discharge. Relationships will be measured using analysis of variance and analysis of covariance procedures.
2. Manpower: Personnel required to gather, collate, and interpret the data are, at a minimum, one 91G Behavioral Science Specialist, one Medical Records Technician, and one Clinical Psychologist.
3. Funding: Not applicable.
4. Number of subjects enrolled to date: 308
5. Number of subjects enrolled during reporting period: 171
6. Adverse reactions: None.

Progress: Pre-treatment, discharge and partial follow-up data have been collected on 308 subjects. Analysis of this data is pending the acquisition of an appropriate statistical capacity for the Eisenhower computer system.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-28		Status: Ongoing	
Title: Reliability and Agreement of Reports of Children's Symptoms.					
Start Date: Apr 84			Est Comp Date:		
Principal Investigator(s)			Facility:		
Peter S. Jensen, MD, MAJ, MC			Eisenhower Army Medical Center		
Michael W. Bain, MD, LTC, MC			Associate Investigators:		
Dept/Svc:			Stephen N. Xenakis, MD, LTC, MC		
Psychiatry-Neurology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Mar 85	
				Review Results Continue	

Study Objective: To examine the effects of parent and child gender and parental depressive symptoms on the reliability and agreement of children's and parents' reports of children's symptoms and behavior problems.

Technical Approach: (1) One hundred 2-parent families will be selected from on-post housing lists to participate in a study of children's depressive symptoms. To be eligible, families must have a child age 8-12. Also, 100 parents and children who are referred to the Child, Adolescent and Family Psychiatry Service at DDEAMC will also participate in the study. Both groups of families will be compared vis a vis then reports of children's depressive symptoms (Scales used are well-standardized instruments including the Child Behavior Checklist, the Child Depression Inventory, and the Beck Depression Inventory). Reliability and agreement between mother's, father's and children's reports will be analyzed to determine how these indices are affected by sex of parent and child, and depression in the parent.

(2) Manpower required is limited to the two current principal investigators.

(3) Funding required is to provide computer support and statistical analysis.

(4) No adverse reactions.

(5) Subjects enrolled to date: 90.

Progress: Significant progress has been made in FY 1985. Ninety subjects have been enrolled to date, scoring of the surveys is 75% complete. Statistical analysis will be done over the next quarter, after completion of enrollment of subjects.

Detail Summary Sheet

Date: 17 Oct 85 Prot No.: 84-43 Status: Completed

Title: Participation in Restandardization of Minnesota Multiphasic Personality Inventory.

Start Date: May 84	Est Comp Date: Fall 85
Principal Investigator(s) Frank H. Rath, Jr., PhD., LTC, MSC Jerry R. DeVore, PhD., CPT, MSC	Facility: Eisenhower Army Medical Center
Dept/Svc: Psychology Service Community Mental Health Service	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: The Minnesota Multiphasic Personality Inventory (MMPI) is the most frequently used personality assessment procedure for clinical purposes in the US Army as well as in general health care practice in the US. Developed in the late 1930's, early 1940's it has long been recognized that cultural and demographic changes have altered the normative basis of the MMPI and have made the range of content area covered less comprehensive than desirable. It is necessary to establish new norms for the MMPI for the currently used clinical scales and to develop norms for new clinical scales to be developed (e.g., alcohol and drug abuse, type A behavior, treatment compliance, etc.) with the addition of new content items. It is highly desirable that active duty Army personnel be part of the restandardization sample, as the restandardized MMPI will be used frequently with Army personnel.

Technical Approach: a. Experimental design. This research is not an experiment. It is a population characteristics study. A new form of the MMPI which included all of the old items and over 150 new items was administered to a population of active duty soldiers, most of whom were enlisted trainees in Signal MOS AIT courses.

b. Manpower: The principal investigators changed during the course of the study. Jerry R. DeVore, PhD, CPT, MSC; Amy Flowers, PhD, CPT, MSC; and Frank H. Rath, Jr., PhD, LTC, MSC are now the principal investigators. James N. Butcher, PhD, University of Minnesota, is an associate investigator. Additionally, James Warren, CPT, MSC, assisted in data collection.

c. Funding: No funding was expended for this project during the preceding fiscal year.

d. Number of soldiers enrolled to date: 266

e. Number of subjects enrolled for reporting period: 0

Progress: Testing was completed, data submitted to Dr. Butcher.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 85-30		Status: Ongoing	
Title: Family Risk and Protective Factors: A Prospective Study of Obstetric Patients and Their Families.					
Start Date: Aug 85			Est Comp Date:		
Principal Investigator(s)			Facility:		
Peter S. Jensen, M.D., MAJ, MC			Eisenhower Army Medical Center		
James Maury, MAJ, MS					
Stephen N. Xenakis, M.D., LTC, MC					
Dept/Svc:			Associate Investigators:		
Psychiatry-Neurology/Social Work Service					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: This study will determine the additive effects of stress, lack of social supports, parental history, parental coping skills, and marital communication on complications of pregnancy in the mother and newborn, and effects of these factors on the child's growth and development.

Technical Approach: One hundred nulliparous women in the first or second trimester of pregnancy and their husbands will be invited to participate in the study. Subjects and spouses will complete surveys to determine their level of social supports, stress, coping skills, marital relationships, etc. These families will be followed prospectively through the course of pregnancy, into the child's first year of life. Statistical analyses will be performed to assess the relationship between interior (stress, supports, coping, etc.) variables and outcome measures (complications of pregnancy, child's growth and development, frequency of illness, etc.).

Progress: No data has yet been gathered, no patients entered on protocol.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: May 78	Est Comp Date:
Principal Investigator(s) Kenneth Y. Gleitsmann, M.D., MAJ, MC John Pope, Jr., M.D., LTC, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words: Intraocular Lens Implant Ophthalmology Aphakia Surgery	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Mar 85 Review Results Continue
Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.	

Technical Approach: Currently accepted surgical techniques for cataract extraction and intraocular lens implantation using the operating microscope.

Number of subjects enrolled to date: 544
 Number of subjects enrolled for reporting period: 127

Progress: A very low rate of complications was noted for all lens types and surgeons during this period. The style 70S anterior chamber lens replaced the earlier styles that were associated with a higher complication rate. The 34S posterior chamber lens continues to yield remarkably uncomplicated results as has been the experience nationwide.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 82-13 Status: Completed
 Title: The Efficacy of Single Dose of Metronidazole, Cefoxitin, or Placebo
 in Preventing Wound Infections Following Appendectomy.

Start Date: Jan 82	Est Comp Date: Jun 85
Principal Investigator(s) James A. Classen, M.D., CPT, MC Ross S. Davies, M.D., COL, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/General Surgery	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Jan 85 Review Results Continue
Study Objective: Determine efficacy of single dose antibiotic in emergency appendectomy.	

Technical Approach: Prospective, randomized, double-blind study.

Subjects enrolled to date: 189

Subjects enrolled for reporting period: 75

Progress: Study completed 30 June 1985. Analysis revealed no significant difference between treatment groups. Data suggested a decrease in wound infections following appendectomy as compared to placebo. Results of the study have been submitted for publication to the American Journal of Surgery.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 83-17 Status: Terminated
 Title: Comparison of Efficacy of Metronidazole in an Animal Model.

Start Date: Feb 83		Est Comp Date:
Principal Investigator(s) William M. Steely, M.D., CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Clinical Investigation		Associate Investigators: Ross S. Davies, M.D., COL, MC Richard W. Harris, CPT, MSC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To examine the effects of antibiotics on monomicrobial and polymicrobial abscesses in a rabbit model.

Technical Approach: Sterile plastic perforated capsules were implanted intraperitoneally into New Zealand white rabbits and held 6 weeks to become encased in a layer of connective tissue. An attempt was then made to treat the animals with metronidazole to determine penetration of the antibiotic in sterile capsule. An intravenous catheter in the jugular vein was inserted and maintained for dosing at a rate of 100 mg/kg/day every 8 hours for 7 days. Samples for serum concentrations and capsule fluid concentrations were obtained at 3 and 7 days. Metronidazole concentration was determined by high performance liquid chromatography.

Progress: Pilot study with jugular catheter placement and IV dosing confirmed feasibility of the project. No conclusions can be drawn from these small numbers, however, and the project is now forced to terminate due to loss of microbiology support at Clinical Investigation (per MAJ Harris).

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 83-24 Status: Ongoing
 Title: Assessment of Vertical Banded Gastroplasty in Treatment of Morbid Obesity.

Start Date: Apr 83	Est Comp Date:
Principal Investigator(s) Ross S. Davies, M.D., COL, MC Robert Chadband, M.D., MAJ, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Medicine Psychiatry and Neurology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 85 Review Results Continue
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Study Objective: To determine if vertical banded stapling is an effective treatment modality for morbid obesity, to determine its long term effectiveness and complications, and to determine if it will prevent the detrimental effects of morbid obesity.

Technical Approach: Weight loss post bypass will be studied in each patient and compared to average weight loss from other centers following the same procedure. Psychologic testing post-operative will be compared to pre-operative results to examine patient self-image pre and post weight loss.

Subjects enrolled to date: 75
 Subjects enrolled for reporting period: 46

Progress: Weight loss postoperatively is consistent with reported results from other centers. Only one significant complication has occurred.

Detail Summary Sheet

Date: 18 Oct 85 Prot No.: 83-27 Status: Ongoing
 Title: Microsurgery Skill Lab.

Start Date: Nov 83	Est Comp Date:
Principal Investigator(s) Allan Goodrich, M.D., MAJ, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic	Associate Investigators: Orthopedic Residents
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: In depth exposure to the principles and techniques of microsurgery in a laboratory setting - skills developed being transferable to clinical setting - may also stimulate interest in further research related to field of microsurgery.

Technical Approach: Monthly orthopedic rotation in microvascular surgery for residents with special emphasis on microvascular repair of rat femoral arteries. Surgical application: suture of very small vessels and nerves. The project is being done in periods of 30 to 60 days by one resident and one staff.

Progress: To date eight residents have completed their objective.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 83-33		Status: Ongoing	
Title: Reflux Esophagitis in Morbid Obesity and the Effects of Vertical Banded Gastroplasty.					
Start Date: Jul 83			Est Comp Date:		
Principal Investigator(s) Frank G. Opelka, CPT, MC Ross S. Davies, COL, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Jan 85 Review Results Continue	

Study Objective: To evaluate the potential for reflux esophagitis in the morbidly obese patient, before and after vertical banded gastroplasty.

Technical Approach: In addition to a preoperative history and physical, each patient will be evaluated and scored for symptoms of gastroesophageal reflux according to the method of Iacone et al.

Subjects enrolled to date: 75
Subjects enrolled for reporting period: 45

Progress: There appears to be no change in resting lower esophageal sphincter pressure following the procedure. This correlates with no significant clinical reflux symptoms in the postoperative group.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-25		Status: Ongoing	
Title: Comparison of Thermography and Standard Techniques for Detection, Diagnosis and Tracing of Peripheral Vascular Disease and Disorders Marked by Altered Patterns of Peripheral Blood Flow.					
Start Date: Mar 84			Est Comp Date:		
Principal Investigator(s) Roberto H. Barja, MD, COL, MC Richard A. Sherman, PhD, CPT, MS			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery/Orthopedics Clinical Investigation			Associate Investigators: Robert Anderson, MD, LTC, MC Larry Walker, MD, CPT, MC J. Allan Goodrich, MD, MAJ, MC Larry Donovan, MD, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Mar 85 Review Results	

Study Objective: To determine the optimal utilization of thermography in clinical evaluation of the vascular status of the affected area. This phase of the project is concentrating on correlating near surface blood flow patterns with reports of pain having varied diagnostic etiologies. The aim is to determine whether thermography is a more sensitive and objective method for initially diagnostic and subsequently tracking pain problems with vascular components than current methods.

Technical Approach: Subjects are recorded thermographically as soon as a patient meeting the eligibility criteria requests treatment. This forms a part of the regular work-up for diagnosis of pain in the Orthopedic Clinic. A series of recordings are made as the patient progresses through treatment and follow-up. The results are then compared with the results of the standard clinical evaluation.

Number of subjects enrolled to date: 146

Number of subjects enrolled for reporting period: 97

Progress: Due to restricted manpower at both Eisenhower and Augusta VA, far less progress was made on this protocol than might have been. At Eisenhower, optimal techniques for thermographic monitoring of the progress of a wide variety of diseases having vascular components were developed and tested. Thermography appears to be highly sensitive to intensity of pain when vascular problems exist but not when there are no vascular components of the problem. Formal studies of the effectiveness of thermography in monitoring carpal tunnel syndrome has begun. Thermography has been shown to be a sensitive, valuable tool in the laboratory for monitoring the heat (and, thus, likely vascular flow) of flap edges during surgery. We will continue this portion of the study with more patients next year. We will also follow the patients after surgery so we can evaluate correlations between thermographic patterns and flap viability and survival.

Detail Summary Sheet

Date: 1 Oct 85	Prot No.: 84-41	Status: Ongoing
Title: Clinical Investigation of the Long Term Effects of Arthroscopic Knee Surgery in the Military Hospital Population.		
Start Date:	Est Comp Date:	
Principal Investigator(s)	Facility:	
LeRoy R. Fullerton, M.D., LTC, MC	Eisenhower Army Medical Center	
Dept/Svc:	Associate Investigators:	
Surgery/Orthopedic Surgery		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To analyze the results in patients treated with knee surgery under arthroscopic surgical control during the period 1 January 1980 to 15 July 1983 at Ft Benning, GA.

Technical Approach: A survey has been done of 100 patients treated by arthroscopic surgery.

Progress: The results of this questionnaire are being analyzed. This report will be completed in FY 86.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 84-42 Status: Ongoing
 Title: Clinical Investigation of Femoral Neck Stress Fractures.

Start Date:	Est Comp Date:
Principal Investigator(s) LeRoy R. Fullerton, M.D., LTC, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic Surgery	Associate Investigators: Harry Snowdy, MD, Orthopedic Dept, Univ of Texas, San Antonio
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To analyze the natural history of a group of patients who sustained femoral neck stress fractures while training at Ft Benning, GA during the period July 1979 to July 1983.

Technical Approach: Questionnaires have been sent to all patients. Examination, when possible of 48 patients with 53 femoral neck stress fractures has been done.

Progress: Report is nearing completion as nearly all data is in. Completion will be in FY 86.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 84-45 Status: Ongoing
 Title: Endoscopic Training Lab.

Start Date: Apr 84	Est Comp Date:
Principal Investigator(s) Richard M. Satava, M.D., LTC, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: Entry level acquaintance with endoscopic skills. The performance of both diagnostic and therapeutic endoscopy on laboratory animals (dogs) in order to develop clinical skills in endoscopy. Also, creation of clinical gastrointestinal entities (pathology, surgical procedures) which can be studied endoscopically for the purpose of training and research.

Progress: There are currently 9 of the anticipated 15 animal models completed and being utilized for surgical resident endoscopy training; these include models of Nissen fundoplication, gastric polyps, antrectomy and Bilroth 1 anastomosis, subtotal gastric resection with Bilroth 2 anastomosis, vertical banded gastroplasty, cholecystoduodenostomy, gastroenterostomy, right hemicolectomy, colectomy with ileo-anal anastomosis. These animals have been maintained for the FY 85.

There is concurrent training of surgical residents in the PGY-3 level of surgical endoscopic procedures. Receipt of equipment in June 1985 allowed for greater implementation of the training schedule. Video equipment has arrived in September 1985 and will be adapted to the endoscopic equipment for further utilization.

Contact has been made with directors of Surgical Endoscopy in other Army Medical Centers with a view to presenting a Surgical Endoscopic Symposium, which would utilize the facilities of the laboratory and the prepared animal models as an integral part of the symposium.

Detail Summary Sheet

Date: 2 Oct 85 Prot No.: 84-46 Status: Completed
 Title: Rectal Mucosectomy With Hydrostatic Dissection.

Start Date: May 84		Est Comp Date: Oct 85
Principal Investigator(s) Richard M. Satava, M.D., LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$350.00	Periodic Review Results

Study Objective: To develop a technique of dissecting the rectal mucosa from the underlying muscularis mucosa without excessive blood loss.

Technical Approach: Rectal mucosectomy by hydrostatic dissection using a solution of 1% xylocaine and epinephrine (1:1000) provides a nearly bloodless method of removing rectal mucosa for an ileo anal pullthrough procedure.

Progress. Nine animals (swine) were completed, with two complications (ileal necrosis) occurring in two animals; however, these complications were not a result of the mucosectomy but rather the result of poor blood supply to terminal ileum. One additional animal had slough of a portion of the ileal mucosa which later regenerated without sequellae. The total cost of the project was \$350, the majority of expenditures being purchase of animals. The protocol will be completed on 1 Oct 85, and data compiled for submission for publication. Preliminary findings demonstrate excellent results with: 1) an average operative blood loss of 37.5cc, 2) mucosal dissection time of 26 minutes, and 3) post-op blood loss of 35cc. These findings indicate that hydrostatic-dissection is an effective means of performing rectal mucosectomy.

Detail Summary Sheet

Date: 2 Oct 85		Prot No.: 84-47		Status: Completed	
Title: Omental Splenic Autotransplantation and Near Total Splenectomy - Protective Effect Against Pneumococcal Bacteremia.					
Start Date: May 84			Est Comp Date:		
Principal Investigator(s) Richard M. Satava, M.D., LTC, MC William M. Steely, M.D., LTC, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery Clinical Investigation			Associate Investigators: Ross S. Davies, M.D., COL, MC Richard W. Harris, MAJ, MS		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: a) To compare two different methods of splenic tissue preservation, and b) to establish the protective effect of a small segment of spleen attached to its own vascular pedicle (near total splenectomy) and autotransplanted spleen against a challenge S. pneumonia.

Technical Approach: Four groups of rats were divided into total splenectomy, partial (40%) splenectomy, splenectomy with 30% autotransplant, and Sham (no splenectomy). At 16 weeks, all rats were challenged with a lethal dose of strep pneumonia and observed for death and five rats of each group were analyzed for septicemia (blood cultures draw with 5, 24, 40 and 72 hours).

Progress: Mortality for each group above were 4%, 5%, 27% and 63% indicating both partial splenectomy and autotransplanted spleen afforded protection from sepsis. Also implied is that the greater the amount of residual splenic tissue, the greater the protection against death from septicemia. Blood cultures indicated that the transplanted spleen was able to afford some protection against bacteria, explaining the mechanism of action for splenic preservation.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 84-72		Status: Completed	
Title: Effects of Epinephrine on Epidural Fentanyl and Hydromorphone for Postoperative Analgesia.					
Start Date: Sep 84			Est Comp Date: Aug 85		
Principal Investigator(s) Edson O. Parker, III, LTC, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery/Anesthesia			Associate Investigators: Sheryl J. Bartell, MAJ, MC G. Lee Brookshire, CPT, MC		
Key Words: Analgesics; Fentanyl, Sufentanil, Hydromorphone; Anesthetic; Technique, epidural; Pain, postoperative					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To assess the effects on the intensity and duration of postoperative analgesia and any other known side effects of epidural narcotics by adding epinephrine to a solution of either fentanyl, sufentanil, or hydromorphone injected in the epidural space.

Technical Approach: After the drug is injected, the epidural catheter will be removed from the back. Each patient will then be observed by one of the investigators after the injections, each 15 minutes for the first hour, then each hour for the next 5 hours for fentanyl and 15 hours for hydromorphone. Observations will be made and recorded for absence, presence, degree of, and treatment for abnormalities in blood pressure, heart rate, respiratory rate, pain, nausea, vomiting, pruritus, somnolence and respiratory depression.

Number of subjects enrolled to date: 56

Number of subjects enrolled for reporting period: 49

Adverse effects: No clinically significant adverse effects.

Progress: The results of this study suggest that epidural administration of highly lipid-soluble opiates in a dose equipotent to 10 mg morphine is a safe effective method of postoperative analgesia. Furthermore, the addition of epinephrine does not prolong the analgesia and may increase the incidence of undesirable side effects. Even when respiratory depression occurred, however, it was mild, associated with an increase in PCO₂ of 11-15 mmHg, without a decrease in respiratory rate. Fentanyl and sufentanil appear safe and effective, but of such short duration that their administration by continuous infusion may be more appropriate. Hydromorphone without epinephrine, because of its long duration of analgesia and absence of undesirable side effects, appears to be clinically a most useful epidural opiate for postoperative analgesia, even when used in a single injection technique.

Parker EO, Brookshire GL, Bartel SJ: Effects of epinephrine on epidural fentanyl, sufentanil and hydromorphone for postoperative analgesia. Anesthesiology Sep 1985; 63(3A):A235.

Same title paper to be presented to Annual Meeting Am Soc Anesthesiologists, San Francisco, CA, 16 Oct 1985.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 85-1 Status: Ongoing
 Title: Implantable Artificial Anal Sphincter (Phase I)

Start Date: Dec 84	Est Comp Date:
Principal Investigator(s) Michael P. Byrne, MAJ, MC Richard M. Satava, LTC, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To develop a hydraulic artificial anal sphincter and implant the sphincter in animals with abdominal or perineal colostomies in order to achieve fecal continence of the stomas.

Technical Approach: Low anterior resection accomplished in standard fashion. Then Group 2 animals have Hartman's procedure with anal sphincter placed intra-abdominally just proximal to colostomy and wrapped with omentum. Group 3 animals have an endo-rectal pullthrough procedure, with the artificial sphincter just proximal to the anastomosis (located at the pelvic floor of the perineum).

Progress: Group 1 and Group 2 animals are complete. Seven of 10 Group 3 animals are complete with protocol completion date of Nov 85. Data will be fully analyzed and submitted for publication to appropriate journal.

Detail Summary Sheet

Date: 18 Oct 85 Prot No.: 85-2 Status: Ongoing
 Title: AML Porocoat^R Acetabular Cup Investigation.

Start Date: Jan 85		Est Comp Date:
Principal Investigator(s) Timothy R. Young, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedics		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To develop a satisfactory system for resurfacing the acetabular fossa. To increase hip joint range of motion and eliminate pain.

Technical Approach:

Progress: No patients enrolled to date. Awaiting instrumentation to be developed soon.

Detail Summary Sheet

Date: 2 Oct 85 Prot No.: 85-5 Status: Ongoing
Title: Advanced Trauma Life Support Course.

Start Date: Jan 85	Est Comp Date:
Principal Investigator(s) Robert Brigham, LTC, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To provide training for physicians who are not dealing with major trauma on a day-to-day basis, and who may have to evaluate the seriously injured patient during the period immediately after injury. Also, it is intended to provide the basic knowledge and skills necessary to identify those patients whose need is for rapid assessment, resuscitation, and stabilization.

Technical Approach:

a. Design: The Advanced Trauma Life Support Course is a two day training session in which participants are given didactic instruction followed by practical skill stations and an animal lab. Testing is accomplished by a written exam and a practical exercise in which a simulated trauma victim is resuscitated.

b. Manpower: Requirements are as follows:

- Course Director (1 MC)
- Course Administrator (MS)
- Instructors (6 MC)
- Logistical Support (2 EM)
- Moulage patients (4 EM)

c. Funding: Administrative cost derived from Office of Medical Education.

Progress: The project has been a tremendous success. We have fully trained 14 instructors and 13 providers in the Advanced Trauma Life Support Course.

Detail Summary Sheet

Date: 18 Oct 85 Prot No.: 85-15 Status: Ongoing
 Title: The Treatment of Segmental Bone Loss in Rabbit Femora with Alveograft[®].

Start Date:		Est Comp Date: Jun 86
Principal Investigator(s) Larry T. Donovan, CPT, MC J. Allan Goodrich, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic Surgery		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if union can be achieved after segmental resection of bone from rabbit femora using a non-resorbable ceramic bone grafting implant as a scaffold for bone ingrowth with and without supplemental autogenous bone graft from the animal's iliac crest.

Technical Approach: Rabbits will undergo segmental resection of 10 and 20% of the femoral diaphysis to simulate traumatic loss of bone. These defects will be replaced by Alveograft, a non-resorbable ceramic bone grafting implant material.

Progress: Study has been held up awaiting arrival of blocks of Alveograft, a new product. These will arrive around the first of December 1985 and we will start work at that time.

Detail Summary Sheet

Date: 3 Oct 85 Prot No.: 85-36 Status: Ongoing
 Title: Implantable Artificial Anal Sphincter (Swine) (Phase II).

Start Date: Nov 85		Est Comp Date:
Principal Investigator(s) Richard M. Satava, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Clinical Investigation		Associate Investigators: Michael P. Byrne, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Phase II will focus on developing the technique of implanting the sphincter in the pelvis, and overcoming the minor technical complications associated with intraabdominal implantation. In addition, by using a commercially available valve and reservoir, the entire sphincter mechanism will be investigated as a totally implantable system.

Technical Approach:

Progress: Approved in late Sep, study not yet implemented.

Detail Summary Sheet

Date: 16 Oct 85 Prot No.: 85-37 Status: Ongoing
 Title: A Comparison of Sympathetic Block Versus Adenosine Monophosphate in the Treatment and Prevention of Shingles and Post Herpetic Neuralgia.

Start Date:		Est Comp Date:	
Principal Investigator(s)		Facility:	
G. Lee Brookshire, MD, CPT, MC		Eisenhower Army Medical Center	
Dept/Svc:		Associate Investigators:	
Surgery/Anesthesia and Operative Svc		Harvey Sklar, MD, Englewood, NJ	
Key Words:		John Cook, MD, LTC, MC	
		Marshall Guill, MD, LTC, MC	
		James K. Aton, MD, COL, MC	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results	

Study Objective: To assess in a placebo controlled randomized, double blinded study if AMP or sympathetic blockade is more effective for treating acute zoster and preventing post herpetic neuralgia. Secondly, in a crossover design to determine the effectiveness of AMP in the treatment of post herpetic neuralgias (treatment failures).

Technical Approach:

Progress: Study locally approved late Sep, not yet implemented.

Detail Summary Sheet

Date: 21 Oct 85 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: Nov 80	Est Comp Date:
Principal Investigator(s) Brian T. Nolan, MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 85 Review Results Continue
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Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens. Presently, the lenses used have been a Pannu Anterior/Posterior Chamber Lens, an IOLAB J-Loop Lens, the McGhan 34S Modified Sheet Lens and a Liteflex Lens. McGhan/3M models 30, 34S, and 77.

Number of subjects enrolled to date: 361

Number of subjects enrolled for reporting period: 76

Progress: Regular follow-up continues on all patients consistent with the guidelines given by the manufacturers of the implants.

Detail Summary Sheet

Date: 21 Oct 85	Prot No.: 82-41	Status: Terminated
Title: Correction of Myopia Using the Fading Technique.		
Start Date: May 82	Est Comp Date:	
Principal Investigator(s) Glenn C. Griffiths, M.D., CPT, MC	Facility: USA MEDDAC, Ft Benning, GA	
Dept/Svc: Family Practice Surgery/Ophthalmology, Optometry	Associate Investigators: Thomas W. Grabow, M.D., LTC, MC William T. Nimmons, O.D., CPT, MSC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 85 Review Results Continue

Study Objective: To determine if training the eye to focus at progressively greater distances results in improvement in myopia.

Technical Approach:

1. Test visual parameters of subjects.
2. Subjects begin fading technique using lens system.
3. Vision testing 3 days per week.
4. Retest visual parameters of subjects at 6 and 12 months after training completed.

Number of subjects enrolled to date: 0

Progress: This study ws terminated on 12 August 1985 at the request of the principal investigator.

Detail Summary Sheet

Date: 21 Oct 85 Prot No.: 83-1 Status: Terminated
 Title: Application of Screening Procedure to Determine the Etiology of Microcytosis With or Without Anemia.

Start Date: Oct 82	Est Comp Date:
Principal Investigator(s) Ronald G. Albright, Jr., M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Mar 85 Review Results Continue

Study Objective: To evaluate the ability of simple calculations made from information found on the routine Coulter CBC slip to predict the etiology of microcytosis with or without anemia.

Technical Approach: Chart review.

Progress: Due to the PCS of MAJ Albright, this study has been terminated.

Detail Summary Sheet

Date: 21 Oct 85 Prot No.: 83-2 Status: Completed
 Title: Remarried Families: Adaptability and Cohesion.

Start Date: Nov 82	Est Comp Date:
Principal Investigator(s) Perry L. Wolf, III, CPT, MSC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Social Work Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Feb 84 Review Results Continue

Study Objective: To study the relationship between family structure and family adaptability and cohesion. The relationship of the intervening variables -- discipline, mythology, and loss -- with adaptability and cohesion will be studied. Role theory and family systems theory will provide a theoretical framework.

Technical Approach: This study will investigate the psychological meaning of adolescent attributes to his/her biological parent and step-parent by comparing the adolescent's appraisal of them along the lines of evaluation, activity, and potency. Each family structure will include a biological mother, her biological child and either a biological father or a step-father. The major independent variable in this study will be defined as family membership in REM family or a biological parent family. Four instruments will be used to collect data on the other study variables.

Number of subjects enrolled to date: 230

Progress: Study is complete. The written report is finished and needs to be buffed and critiqued. Final draft expected to be in sometime in December 1985.

Detail Summary Sheet

Date: 22 Oct 85		Prot No.: 84-7		Status: Completed	
Title: How do Patients Choose Their Physician? The Effect of Patient Knowledge of Family Practice on Their Choice of Physicians.					
Start Date:			Est Comp Date:		
Principal Investigator(s) John W. Saultz, M.D., CPT, MC			Facility: USA MEDDAC, Fort Benning, GA		
Dept/Svc: Family Practice			Associate Investigators: James B. Wright, M.D., MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: This study is designed to measure the impact of pre-printed information sheets on whether a family chooses to join Family Practice or not. To gather basic data on the characteristics, i.e., background, education, training of those individuals who do choose to sign up for Family Practice.

Technical Approach: 1) Control group given no information. 2) Group given questionnaire only. 3) Group given questionnaire and pre-written information about Family Practice by American Academy of Family Physicians.

Number of subjects enrolled to date: 466

Progress: No significant difference was noted in the rate of enrollment in the Family Practice Clinic among the three study groups.

Detail Summary Sheet

Date: 21 Oct 85 Prot No.: 84-23 Status: Ongoing
 Title: Smoking and Attrition in Infantry One Station Unit Training (OSUT).

Start Date: Feb 84		Est Comp Date:
Principal Investigator(s) John A. Parker, Jr., M.D., MAJ, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators:
Key Words:		Wayne G. Stanley, MD, CPT, MC Frederick N. Dyer, PhD
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic 15 Mar 85 Review Results Continue

Study Objective: To determine whether smoking adversely affects successful completion of Infantry One Station Unit Training (OSUT).

Technical Approach: Administrative questionnaires regarding smoking given to troops of Infantry One Station Unit Training (OSUT). These troops will be followed until the conclusion of OSUT.

Number of subjects enrolled to date: 1000

Progress: Data gathering is in progress with approximately one-half of total desired enrolled. Will continue with data gathering and analyze all results once it is concluded.

Detail Summary Sheet

Date: 21 Oct 85 Prot No.: 85-6 Status: Ongoing
 Title: Evaluating Communication Skills of Medical Students.

Start Date:		Est Comp Date:
Principal Investigator(s) Edward M. Friedler, MAJ, MC		Facility: MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators: Perry Wolf, CPT, MSC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 85 Review Results Continue

Study Objective: 1) Observe specific communication behaviors of medical students at the beginning of their Family Medicine Clerkship; 2) present a structured experiential course on techniques of communication skills; 3) observe the students' specific communication behaviors after the course; 4) study the associations of student communication behaviors with their success in meeting the course objectives.

Technical Approach: Videotaping.

Number of subjects enrolled to date: 20

Progress: All subjects should be enrolled by June 1986.

Detail Summary Sheet

Date: 21 Oct 85		Prot No.: 85-7		Status: Completed	
Title: The Use of C Reactive Protein as a Screening Test for Bacterial Infections in an Acute Respiratory Disease (ARD) Setting.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Neal D. Johnson, CPT, MC			MEDDAC, Ft Benning, GA		
Dept/Svc:			Associate Investigators:		
Family Practice					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To do a retrospective analysis of C reactive protein results of all patients admitted to the ARD ward at Martin Army Community Hospital over a three to four month time period and determine if it is a valid predictor for bacterial disease.

Technical Approach: Patients admitted to the ARD ward between October 1984 through January 1985 had a C reactive protein drawn. At the end of that time all individual records were reviewed along with their corresponding results of C reactive protein levels. At that time the sensitivity of C reactive protein based on its reactivity was correlated as to whether or not it was predictive in patients who developed subsequent bacterial infections. The type of lab tests done were the undiluted rapid latex agglutination slide test for quantitative determination of C reactive protein produced by ICL Scientific Laboratories.

Number of subjects enrolled to date: 300

Progress: CPT Johnson completed gathering data in April before his PCS to Germany. Final analysis of the data will be completed at this new duty station.

Detail Summary Sheet

Date: 21 Oct 85 Prot No.: 85-8 Status: Completed
 Title: Leading Edge Needle Aspiration in the Diagnosis of Cellulitis.

Start Date: Nov 1984		Est Comp Date: Sep 1985
Principal Investigator(s) Ted Epperly, CPT, MC		Facility: MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To systematically aspirate 100 successive cases of adult cellulitis using a standard procedure and identifying the percentage of positive aspirates and the organisms isoated.

Technical Approach: The workup will consist of filling out a questionnaire (health care provider) and obtaining a leading edge cellulitis aspiration, CBC, ESR, and blood culture.

Number of subjects enrolled to date: 100

Progress: The study was completed on 7 September 1985 with the 100th case. A paper will be written and submitted through the Clinical Investigation Service for publication in a major journal.

Detail Summary Sheet

Date: 21 Oct 85		Prot No.: 85-20		Status: Ongoing	
Title: Use of a "Child Safety Kit" to Improve Maternal Knowledge of Child Safety Practices.					
Start Date: Dec 1984			Est Comp Date: Dec 1985		
Principal Investigator(s) Theodore G. Brna, Jr., CPT, MC			Facility: USA MEDDAC, Ft Benning, GA		
Dept/Svc:			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine whether antepartum instruction in education (in the form of a "Child Safety Kit") will improve maternal knowledge of child safety practices as demonstrated by improvement in scores on a pre and post delivery test.

Technical Approach: The study group will consist of 400 primiparous mothers. In the 3-5 day postpartum period each mother will be given a questionnaire to determine their "baseline" knowledge in certain areas of child safety. Upon leaving the hospital, half of the new mothers will be given a "Child Safety Kit" according to an assigned random digit number in a sealed envelope. At the six week follow-up visit for her infant, each mother will be given the same questionnaire with addition of one subjective question about the kit's effectiveness.

Number of subjects enrolled to date: 220

Progress: Approximately half way through collecting data. Data should be completed by 30 December 1985, at which time the data will be analyzed and results used in writing a paper.

Detail Summary Sheet

Date: 21 Oct 85		Prot No.: 85-21		Status: Ongoing	
Title: Knowing the Child's Gender Prior to Birth: Disentangling the Effect of Infant Cues and Parental Behavior on Sex Role Stereotyping.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Joanne Sweeney			USA MEDDAC, Ft Benning, GA		
Dept/Svc:			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine if a couple's knowledge of their child's gender before the child is born influences their socialization of the child according to sex role stereotypes.

Technical Approach: Subjects were given survey forms twice during the course of their pregnancy and once following the delivery of the child. This required non-invasive procedures with subjects only filling out forms.

Number of subjects enrolled to date: 36 couples (72 subjects).

Progress: Data has all been collected and entered into the computers at Auburn University. At the present time performing various statistical tests of significance (ANOVOS) on the collected data. Probably will start writing results at the end of October.

Detail Summary Sheet

Date: 21 Oct 85		Prot No.: 85-34		Status: Ongoing	
Title: Adolescent Medicine: Attitudes and Skills of Internal Medicine, Pediatric and Family Practice Residents.					
Start Date: Oct 85			Est Comp Date: Jan 1986		
Principal Investigator(s)			Facility:		
Thomas Goodell, CPT, MC			USA MEDDAC, Fort Benning, GA		
Dept/Svc:			Associate Investigators:		
Family Practice					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: This study is an attempt to identify the expectations to provide care and the patient care skills of residents from Internal Medicine, Pediatrics and Family Practice.

Technical Approach: The study consists of a one-time survey evaluating desire and expectations to care for certain age groups, perceived ability to care for certain health problems within these age groups and perceived need for certain patient care skills and their ability at these same skills. The subject population consists of all Internal Medicine, Pediatric and Family Practice residents in US Army training programs.

Number of subjects enrolled to date:

Progress: Study approved locally in late FY 85, no reportable data.

Detail Summary Sheet

Date: 21 Oct 85		Prot No.: 85-35		Status: Ongoing	
Title: The Influence of Family Members and Peers on the Duration of Location for Low Income Women Living in a Military Community..					
Start Date: Sep 1985			Est Comp Date: Jun 1986		
Principal Investigator(s)			Facility:		
Ms Sharon Barron			USA MEDDAC, Fort Benning, GA		
Dept/Svc:			Associate Investigators:		
Auburn University					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To determine if positive family member and peer attitudes toward breastfeeding are associated with a longer duration of lactation.					

Technical Approach: All primigravidas enrolled in the WIC Program who have indicated a desire to breastfeed will be studied. A preliminary questionnaire will be administered before delivery to determine demographics pertinent to the study. A second questionnaire will be administered when the mother terminates breastfeeding or at 3 months postpartum, whichever occurs first.

Progress: Study approved locally in late FY 85, no reportable data.

Detail Summary Sheet

Date: 15 Oct 84 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: Oct 81	Est Comp Date:
Principal Investigator(s) Ramsey Tarabishy, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Campbell, KY
Dept/Svc: Surgery/Ophthalmology	Associate Investigators: Richard B. Phinney, M.D. CPT, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To provide to cataract patients the latest development in ophthalmic surgery concerning the correction of surgical aphakia.

Technical Approach: Intracapsular or extracapsular cataract extraction followed by the implantation of an anterior chamber lens.

Cost per lens: \$360 each.

Subjects enrolled to date: 45

Subjects enrolled for the reporting period: 18

Progress: No complications noted to date.

Detail Summary Sheet

Date: 7 Oct 85 Prot No.: 85-32 Status: Ongoing
 Title: Histoplasmosis Seroconversion Study.

Start Date: Sep 85	Est Comp Date: Dec 85
Principal Investigator(s) Mark J. Wolcott, CPT, MS	Facility: USA MEDDAC, Ft Campbell, KY
Dept/Svc: Pathology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine a seroconversion rate and time frame for histoplasmosis on newly arrived military personnel into the Ft Campbell, KY area.

Technical Approach: On 9 Sep 85 the project was started with the collection of blood samples from volunteer personnel that were inprocessing through the replacement detachment. A total of 84 personnel volunteered but two withdrew before an adequate specimen was obtained leaving 82 personnel for the project.

Summary of experimental design: a sample of newly arrived personnel into Ft Campbell are sampled for a blood specimen upon arrival, one month and two months later. The serum antibody levels to IgM, IgG and IgE will be measured to determine a rate of seroconversion and type of antibody response to exposure to histoplasmosis. The test procedure will be a EIA (ELISA) type test.

Manpower: CPT Mark Wolcott

Funding: 2660 supply money not expected to exceed \$30.00.

Number of subjects enrolled to date: 82.

Nature of adverse reactions: one volunteer fainted during initial blood collection and was not further enrolled.

Progress: First sampling completed.

Detail Summary Sheet

Date: 23 Oct 85 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: Jul 81		Est Comp Date:
Principal Investigator(s) Milne, Henry L, M.D., CPT, MC		Facility: USA MEDDAC, Ft Jackson, SC
Dept/Svc: Surgery/Ophthalmology		Associate Investigators: Dean Jacobs, M.D., MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 85 Review Results Continue
Study Objective: Insertion in selected patients of Tennant Anterior Chamber Anchor Lens.		

Technical Approach: Using routine intracapsular cataract techniques, the lens would be inserted prior to final closure of the wound.

Subjects enrolled to date: 303
 Subjects enrolled for reporting period: 116

Progress: CPT Milne: one sublux lens complication; however, was able to successfully replace the lens.

MAJ Jacobs: One endophethal mitis, one vitreous hemorrhage; both resulted in blindness. One dislocated IOL and one wound dehiscence; both were repaired to 20/20 vision.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 84-48 Status: Ongoing
 Title: Sudden Death in Young Adults With Unrecognized Heart Disease.

Start Date: Feb 85		Est Comp Date:
Principal Investigator(s) Wesley Covitz, M.D. Albert C. Molnar, M.D., COL, MC		Facility: USA MEDDAC, Ft Jackson, SC Medical College of Georgia
Dept/Svc: Pediatric Cardiology		Associate Investigators:
Key Words: Chest pain, Cardiac disease, Screening program		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1. To identify basic trainees with chest pain who are at risk for sudden death due to previously unrecognized cardiac disease; 2. to determine which elements of history, physical examination, and noninvasive laboratory evaluation are most likely to identify those who are at risk; and 3. to develop a sensitive screening program which may be practically applied to basic trainees and high school and college athletes.

Technical Approach: Basic trainees who sought medical attention for chest pain were systematically evaluated to detect heart disease and identify risk factors. Subjects were drawn from a potential population of 14,000 trainees. They were equally divided by sex and race. Their mean age was 21 ± 3.8 years. The evaluation consisted of a brief screening exam (phase I), a comprehensive history and physical (phase II) and echocardiography and exercise radionuclide ventriculography (phase III). No funding has been received from the Army for this project. There were no adverse side effects.

Number of subjects enrolled to date: 218.

Progress: Phase I exams were sufficient to exclude heart disease in 114 trainees (52%). An additional 54 subjects (25%) were returned to duty after phase II. Of the 50 soldiers who entered phase III, 20 were found to have cardiovascular disease (9% of total group). The most common noncardiac causes of chest pain were musculoskeletal 104 (48%) and respiratory 27 (12%). Angina was an infrequent complaint 8/218 (4%), but 3/8 had significant heart disease. The most frequent reasons for referral to phase III were exercise induced syncope (20/50), suspected mitral valve prolapse (10/50), and heart murmur (9/50). Mitral valve prolapse was confirmed in 15/20 trainees with heart disease. Of those with prolapse, 7 had exercise induced syncope, one had exercise induced ventricular arrhythmia, and one had a hypertensive response to exercise. The 5 subjects without prolapse had exercise induced hypertension (2), 2^o heart block with inadequate heart rate response to exercise, exercise syncope with subendocardial ischemia, and exercise syncope with abnormal take off of the left coronary. Angina, symptomatic mitral valve prolapse, and exercise induced syncope were important predictors of heart disease in basic trainees with chest pain. The project was temporarily discontinued during the summer because of lack of funding. If all the appropriate approvals are obtained it will resume by mid October or early November of this year.

Detail Summary Sheet

Date: 7 Oct 85	Prot No.: 85-25	Status: Completed
Title: The Impact of Decisional Control on Patient Satisfaction.		
Start Date: June 1985	Est Comp Date: Aug 85	
Principal Investigator(s) Valerie E. Biskey, MSN, MAJ, AN	Facility: MEDDAC, Ft Jackson, SC	
Dept/Svc: Nursing	Associate Investigators: Suzette Fattal, MSN, LTC, AN	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if patient participation in health care decisions is related to increased satisfaction with nursing care.

Technical Approach: Thirty patients were selected to participate in this research - 15 patients were the experimental group and 15 patients were the control group. Appointments were scheduled by the associate investigator and were seen in IMC once a month for three months (Jun-Aug 85). Patients were followed very closely and ensured scheduled visits to the clinic.

Manpower: LTC Suzette Fattal, AN.

Number of subjects enrolled to date: 30.

Progress: All subjects were seen and followed by their essential hypertension and weight as instructed by the principal investigator. The control group was given specific information to change medications, increase physical activities, and restrict salt and fatty foods. The experimental group was actively encouraged to participate; recommend medicine changes, increase or decrease activities, and take actions under the supervision of the associate investigator. All subjects appeared motivated and genuinely interested to participate in the study.

Data for the nursing research study was collected and sent to the principal investigator, MAJ Biskey.

MAJ Biskey is in the process of finishing the research paper.

Detail Summary Sheet

Date: 1 Oct 85		Prot No.: 85-19		Status: Terminated	
Title: Patients' Perineal Pain Perception Following the Use of Cold Versus Warm Postpartum Sitz Baths.					
Start Date: May 1985			Est Comp Date:		
Principal Investigator(s)			Facility:		
Rosemary L. Janofsky, Graduate Student			MEDDAC, Ft Knox, KY		
Dept/Svc:			Associate Investigators:		
Nursing			Priscilla H. Czachowski, MAJ, AN		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: Attempt to determine if cold water sitz baths will be more effective than warm water sitz baths in relieving postpartum perineal pain.

Technical Approach: The subjects will compose two groups of 15 postpartum women, who have delivered a baby within 12 hours prior to their first sitz bath and have had an episiotomy during the vaginal birth.

Progress: Reply from Asst AG at MEDDAC, Ft Knox, KY, stated there was no record of principal investigator.

Detail Summary Sheet

Date: 7 Oct 85 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: Oct 80		Est Comp Date:
Principal Investigator(s) William G. Carey, M.D., MAJ, MC		Facility: USA MEDDAC, Ft Rucker, AL
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words: Intraocular Lens Aphakia Implant Surgery Ophthalmology		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The objective of the ongoing FDA study is to determine the safety of the intraocular lens implant in the human eye.

Technical Approach: In all primary implants during this period, the extracapsular cataract approach was used. A style 20 posterior chamber lens manufactured by Surgidev Corporation was placed in the posterior chamber. In all secondary implants, the style 10 anterior chamber lens, by Surgidev Corporation, was used.

Subjects enrolled to date: 266.
 Subjects enrolled for reporting period: 82.

Progress: 68 posterior chamber lenses and 14 anterior chamber lenses.
 Patients are doing well and there are no problems resulting from these lenses.

Detail Summary Sheet

Date: 1 Oct 85 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date:	Est Comp Date:
Principal Investigator(s) Charles S. Tressler, MD, CPT, MC	Facility: USA MEDDAC, Ft Stewart, GA
Dept/Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens.

Number of subjects enrolled to date: 14.

Progress: No adverse reaction to the intraocular lenses used. All were 3M except for one by IOLAB.

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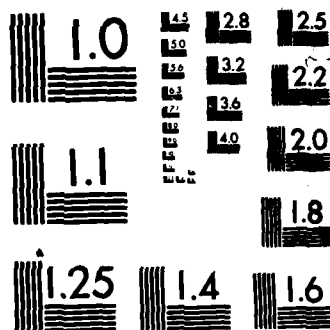
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